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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORPORATION, and HOLOGIC L.P.,

Plaintiffs,

vs.

SENORX, INC.,

Defendant.

AND RELATED COUNTERCLAIMS.

Case No. C08 00133 RMW (RS)

DECLARATION OF KATHARINE L. ALTEMUS IN SUPPORT OF PLAINTIFFS' REPLY BRIEF IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

Date: April 21, 2008
Time: 2:00 p.m.
Courtroom: 6, 4th Floor
Judge: Hon. Ronald M. Whyte

I, Katharine L. Altemus, declare that I am an associate in the law firm Howrey LLP and a member of the bar of this court, and I serve as one of the outside counsel for Plaintiffs Hologic, Inc., Cytyc Corporation and Hologic LP. The following declaration is based on my personal knowledge, and if sworn as a witness I could and would competently testify as to the matters set forth herein.

1. Attached hereto as Exhibit O is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00006590-611, marked Confidential-Outside Counsel Only and submitted under seal.

2. Attached hereto as Exhibit P is a true and correct copy of United States Patent No. 6,413,204.

3. Attached hereto as Exhibit Q is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00004119-128, marked Confidential-Outside Counsel Only and submitted under seal.

4. Attached hereto as Exhibit R is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00006486-497, marked Confidential-Outside Counsel Only and submitted under seal.

5. Attached hereto as Exhibit S is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00000314-318.

6. Attached hereto as Exhibit T is a true and correct copy of an article by R.D. Ashpole, *et al.*, entitled "A New Technique of Brachytherapy for Malignant Gliomas with Caesium-173: A New Method Utilizing a Remote Afterloading System," produced in this litigation by Defendant, Bates numbered SRX-HOL00002292-296.

7. Attached hereto as Exhibit U is a true and correct copy of excerpts from the transcript of the deposition of Colin G. Orton, Ph. D. taken on April 4, 2008, marked Highly Confidential and submitted under seal.

8. Attached hereto as Exhibit V is a true and copy of United States Patent No. 6,482,142.

9. Attached hereto as Exhibit W is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00006616-686, marked Confidential-Outside Counsel Only, and submitted under seal.

10. Attached hereto as Exhibit X is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00007335-7348, marked Confidential-Outside Counsel Only, and submitted under seal.

11. Attached hereto as Exhibit Y is a true and correct copy of excerpts from the transcript of the deposition of William F. Gearhart, taken on April 2, 2008, marked Confidential and submitted under seal.

12. Attached hereto as Exhibit Z is a true and correct copy of excerpts from the transcript of the deposition of Philip Z. Israel, taken on April 2, 2008.

13. Attached hereto as Exhibit AA is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00007202-205, marked Confidential-Outside Counsel Only, and submitted under seal.

14. Attached hereto as Exhibit BB is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00007169-187, marked Confidential-Outside Counsel Only, and submitted under seal.

15. Attached hereto as Exhibit CC is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00007192-201, marked Confidential-Outside Counsel Only, and submitted under seal.

16. Attached hereto as Exhibit DD is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00007323-334, marked Confidential-Outside Counsel Only, and submitted under seal.

17. Attached hereto as Exhibit EE is a true and correct copy of excerpts from the transcript of the deposition of Hologic, Inc. taken on March 18, 2008, pursuant to Fed.R.Civ.P. 30(b)(6), through Glenn I. Magnuson, marked Confidential, and submitted under seal.

18. Attached hereto as Exhibit FF is a true and correct copy of excerpts from the transcript of the deposition of Roy Weinstein taken on April 4, 2008, marked Highly Confidential, and submitted under seal.

19. Attached hereto as Exhibit GG is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00006575-584, marked Confidential-Outside Counsel Only, and submitted under seal.

20. Attached hereto as Exhibit HH is a true and correct copy of excerpts from the transcript of the deposition of Douglas W. Arthur taken on April 4, 2008, marked Highly Confidential, and submitted under seal.

21. Attached hereto as Exhibit II is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00007316-322, marked Confidential-Outside Counsel Only, and submitted under seal.

22. Attached hereto as Exhibit JJ is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL 00002232-233.

23. Attached hereto as Exhibit KK is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00005395-429, marked Confidential-Outside Counsel Only, and submitted under seal.

24. Attached hereto as Exhibit LL is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL5538, marked Confidential-Outside Counsel Only, and submitted under seal.

25. Attached hereto as Exhibit MM is a true and correct copy of excerpts from the transcript of the deposition of Ronald E. Cahill taken on April 18, 2007, in the matter of *Xoft Microtube, Inc. v. Cytyc Corporation, a Delaware corporation, and Proxima Therapeutics, Inc., a Delaware corporation*, filed in the United States District Court, Northern District of California, Civil Action No. CV 05-05312 RMW.

26. Attached hereto as Exhibit NN is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00005563-65, marked Confidential-Outside Counsel Only, and submitted under seal.

27. Attached hereto as Exhibit OO is a true and correct copy of Claim Construction Order filed April 27, 2007, in the matter of *Xoft Microtube, Inc. v. Cytyc Corporation, a Delaware*

corporation, and Proxima Therapeutics, Inc., a Delaware corporation, filed in the United States District Court, Northern District of California, Civil Action No. CV 05-05312 RMW.

28. Attached hereto as Exhibit PP is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00000211-224.

29. Attached hereto as Exhibit QQ is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00005492, marked Confidential-Outside Counsel Only, and submitted under seal.

30. Attached hereto as Exhibit RR is a true and correct copy of the cover page, table of contents page i, and pages 37, 38 and 39 of Form 10-K, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, for the fiscal year ended December 31, 2007, filed by Defendant with the United States Securities and Exchange Commission.

31. Attached hereto as Exhibit SS is a true and correct copy of Form 8-K, Current Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, filed by Defendant dated February 19, 2008.

32. Attached hereto as Exhibit TT is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00002757-2791.

33. Attached hereto as Exhibit UU is a true and correct copy of United States Patent No. 5,931,774, produced in this litigation by Defendant, Bates numbered SRX-HOL00002297-2307.

34. Attached hereto as Exhibit VV is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00002353-2358.

35. Attached hereto as Exhibit WW is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00002359-2370.

36. Attached hereto as Exhibit XX is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00006882-6898, marked Confidential-Outside Counsel Only, and submitted under seal.

37. Attached hereto as Exhibit YY is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00003362-3379, marked Confidential-Outside Counsel Only, and submitted under seal.

38. Attached hereto as Exhibit ZZ is a true and correct copy of a document produced in this litigation by Defendant, Bates numbered SRX-HOL00000406-430, marked Confidential-Outside Counsel Only, and submitted under seal.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed on April 7, 2008, at East Palo Alto, California.

Dated: April 7, 2007

HOWREY LLP

By: /s/
Katharine L. Altemus

HOWREY LLP
Attorneys for Plaintiffs
Hologic, Inc., Cytyc Corporation,
and Hologic LP

Exhibit P

(12) **United States Patent**
Winkler et al.

(10) **Patent No.: US 6,413,204 B1**
(45) **Date of Patent: *Jul. 2, 2002**

(54) **INTERSTITIAL BRACHYTHERAPY APPARATUS AND METHOD FOR TREATMENT OF PROLIFERATIVE TISSUE DISEASES**

(75) Inventors: **Rance A. Winkler**, Atlanta; **Timothy J. Patrick**; **James Stubbs**, both of Alpharetta, all of GA (US)

(73) Assignee: **Proxima Therapeutics, Inc.**, Alpharetta, GA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/293,524**

(22) Filed: **Apr. 15, 1999**

Related U.S. Application Data

(63) Continuation-in-part of application No. 08/900,021, filed on Jul. 4, 1997, now Pat. No. 5,913,813.

(51) **Int. Cl.**[7] **A61N 5/00**
(52) **U.S. Cl.** **600/3**
(58) **Field of Search** 600/1–8

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,324,847 A	6/1967	Zoumboulis	.....	128/1.2
3,872,856 A	3/1975	Clayton	.....	128/1.2
4,417,576 A	11/1983	Baran	.....	128/207.15
4,706,652 A	11/1987	Horowitz	.....	128/1.2
4,754,745 A	7/1988	Horowitz	.....	128/1.2
4,763,642 A	8/1988	Horowitz	.....	128/1.2

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

EP	0340881	11/1989	..... A61N/5/10
EP	0867200	9/1998	
GB	2105201	3/1983	..... A61N/1/06
WO	9210932	7/1992	..... A61N/5/02
WO	9309724	5/1993	..... A61B/17/36
WO	9719723	6/1997	..... A61N/5/00
WO	9812979	4/1998	..... A61B/19/00
WO	9911325	3/1999	
WO	9933515	7/1999	
WO	9942163	9/1999	

OTHER PUBLICATIONS

A. Bex et al., *A System for Focal Intracavitary Irradiation of Bladder Cancer with Remote Iridium–192 Afterloading*, 21 Eur Urol 1992, 245–249 (1992).

Ashpole, R.D. et al., "A New Technique of Brachtherapy for Malignant Gliomas with Caesium–137: A New Method Utilizing a Remote Afterloading System," Clinical Oncology, vol. 2, 333–7 (1990).

Chun, M. et al., "Interstitial Iridium–192 Implantation for Malignant Brain Tumours. Part II: Clinical Experience," *The British Journal of Radiology*, vol. 62, 158–62 (1989).

Garfield, J. et al., "Postoperative Intracavitary Chemotherapy of Malignant Gliomas," *J. Neurosurg.*, vol. 39, 315–22 (Sep. 1973).

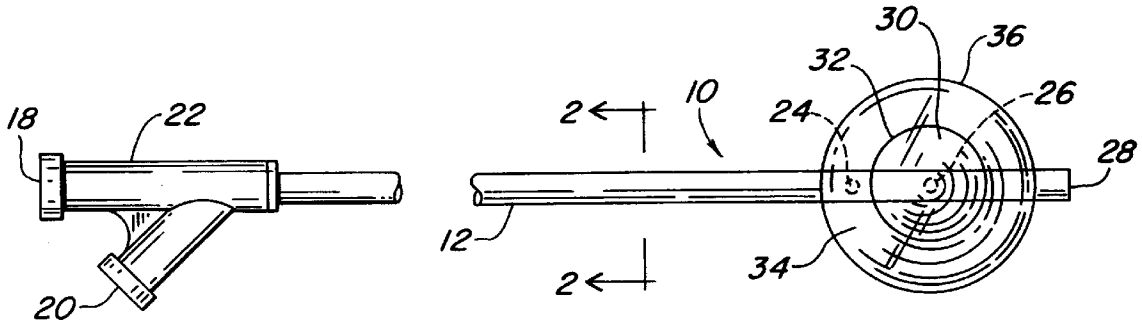
(List continued on next page.)

Primary Examiner—John P. Lacyk
(74) *Attorney, Agent, or Firm*—Thomas J. Engellenner; Ronald E. Cahill; Nutter, McClennen & Fish, LLP

(57) **ABSTRACT**

An interstitial brachytherapy apparatus for delivering radioactive emissions to an internal body location includes a catheter body member having a proximal end and distal end, an inner spatial volume disposed proximate to the distal end of the catheter body member, an outer spatial volume defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume, and a radiation source disposed in the inner spatial volume.

36 Claims, 3 Drawing Sheets



U.S. PATENT DOCUMENTS

4,821,725	A		4/1989	Azam et al. ..... 128/420 A
4,867,741	A		9/1989	Portnoy 604/10
5,084,001	A		1/1992	Van't Hooft et al. 600/3
5,084,015	A		1/1992	Moriuchi 604/96
5,106,360	A		4/1992	Ishiwara et al. 600/2
5,112,303	A		5/1992	Pudenz et al. 604/49
5,152,747	A		10/1992	Olivier 604/93
5,236,410	A		8/1993	Granov et al. 600/12
5,429,582	A		7/1995	Williams 600/2
5,484,384	A		1/1996	Fearnot 600/3
5,503,613	A		4/1996	Weinberger 600/3
5,566,221	A		10/1996	Smith et al. 378/145
5,611,767	A		3/1997	Williams 600/2
5,662,580	A		9/1997	Bradshaw et al. 600/3
5,707,332	A		1/1998	Weinberger 600/3
5,713,828	A		2/1998	Coniglione 600/7
5,720,717	A		2/1998	D'Andrea 604/21
5,764,723	A		6/1998	Weinberger et al. 378/65
5,782,742	A		7/1998	Crocker et al. 600/3
5,785,688	A		7/1998	Joshi et al. 604/141
5,913,813	A	*	6/1999	Williams et al. 600/3
5,924,973	A	*	7/1999	Wenberger 600/3
6,036,631	A		3/2000	McGrath et al. 600/3
6,059,812	A	*	5/2000	Clerc et al. 600/3

OTHER PUBLICATIONS

Gutin, P. et al., "Brachytherapy of Recurrent Malignant Brain Tumors With Removable High–Activity Iodine–125 Sources," *J. Neurosurg.*, vol. 60, 61–8 (1984).

Johannesen, T.B. et al., "Intracavity Fractionated Balloon Brachytherapy in Gilioblastoma," *Acta Neurochir* (*Wien*), vol. 141, 127–33 (1999).

Leibel, S. et al., "The Integration of Interstitial Implantation Into the Preliminary Mangement of Patients With Malignant Gliomas: Results of a Phase II Northern California Oncology Group Trial," *Am. J. Clin. Oncol.* (*CCT*), vol. 10, No. 2, p. 106 (1987).*

Roberts, D. et al., "Interstitial Hyperthermia and Iridium Brachytherapy in Treamtnet of Malignant Glioma," *J. Neurosurg.*, vol. 64, 581–7 (1986).*

Wu, A. et al., "Interstitial Iridium–192 Implantation for Malignant Brain Tumours, Part 1: Techniques of Dosimetry Planning," *The British Journal of Radiology*, vol. 62, 154–7 (1989).*

* cited by examiner

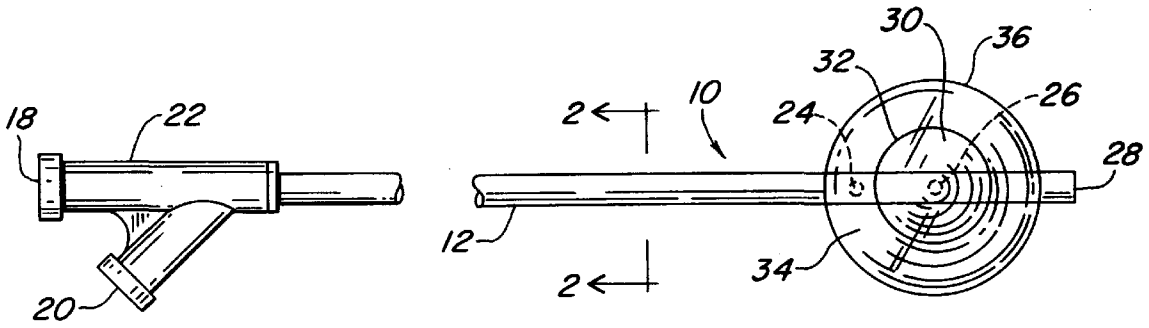


FIG. 1

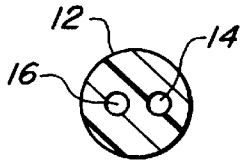


FIG. 2

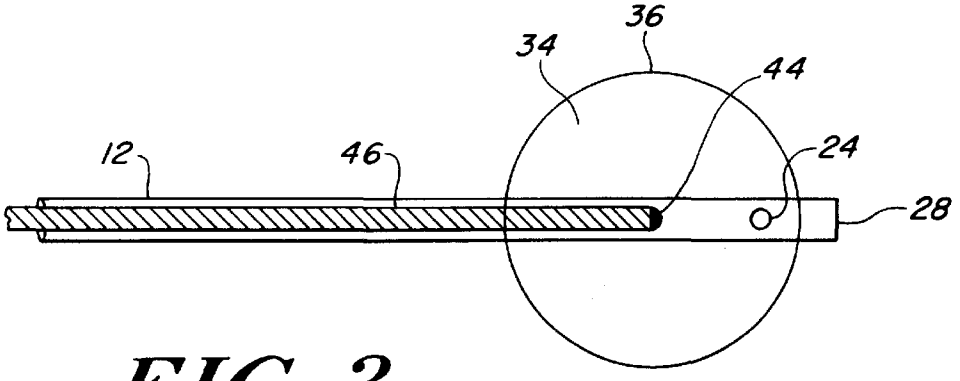


FIG. 3

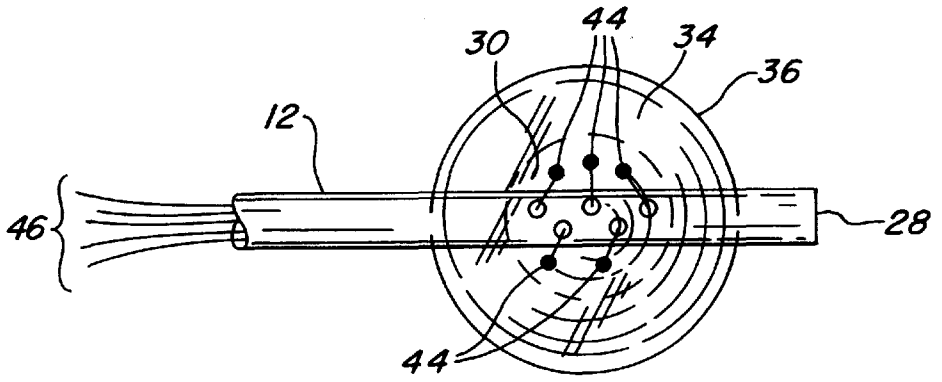


FIG. 4

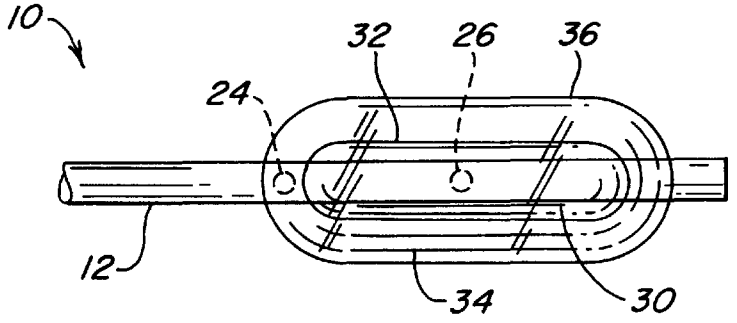


FIG. 5

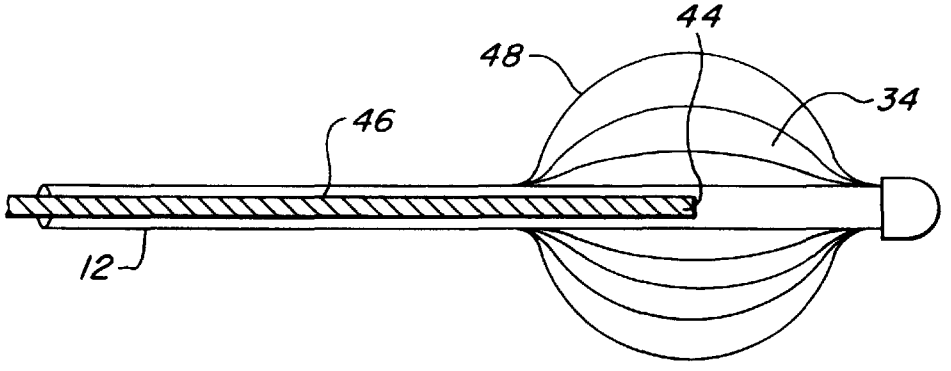


FIG. 6

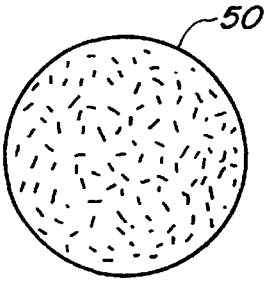


FIG. 7A

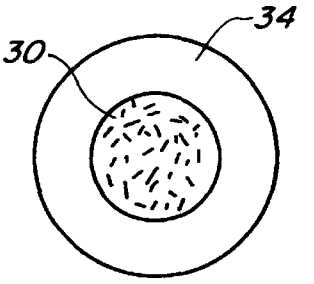


FIG. 7B

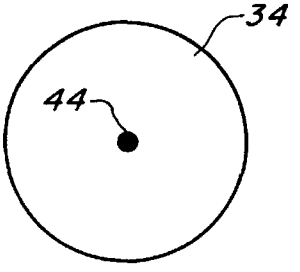


FIG. 7C

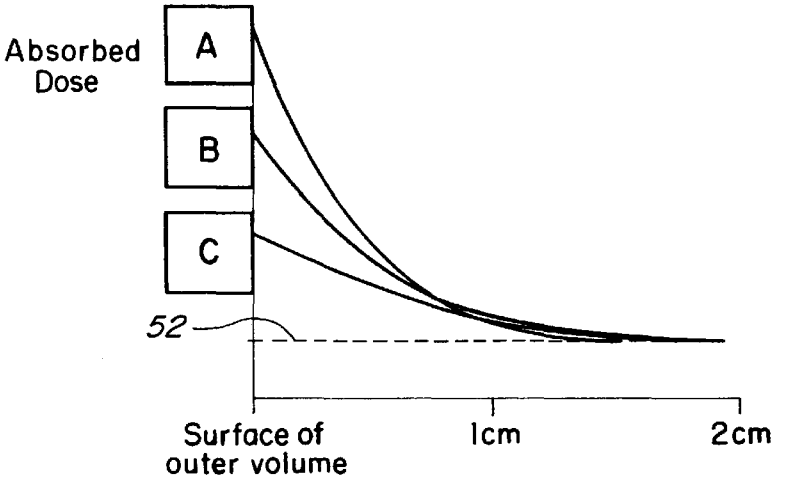


FIG. 7D

INTERSTITIAL BRACHYTHERAPY APPARATUS AND METHOD FOR TREATMENT OF PROLIFERATIVE TISSUE DISEASES

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 08/900,021, filed Jul. 24, 1997, now U.S. Pat. No. 5,913,813 the contents of which are specifically incorporated herein by reference.

BACKGROUND OF THE INVENTION

The invention relates generally to apparatus for use in treating proliferative tissue disorders, and more particularly to an apparatus for the treatment of such disorders in the body by the application of radiation.

Malignant tumors are often treated by surgical resection of the tumor to remove as much of the tumor as possible. Infiltration of the tumor cells into normal tissue surrounding the tumor, however, can limit the therapeutic value of surgical resection because the infiltration can be difficult or impossible to treat surgically. Radiation therapy can be used to supplement surgical resection by targeting the residual tumor margin after resection, with the goal of reducing its size or stabilizing it. Radiation therapy can be administered through one of several methods, or a combination of methods, including external-beam radiation, stereotactic radiosurgery, and permanent or temporary interstitial brachytherapy. The term "brachytherapy," as used herein, refers to radiation therapy delivered by a spatially confined radioactive material inserted into the body at or near a tumor or other proliferative tissue disease site. Owing to the proximity of the radiation source, brachytherapy offers the advantage of delivering a more localized dose to the target tissue region.

For example, brachytherapy is performed by implanting radiation sources directly into the tissue to be treated. Brachytherapy is most appropriate where 1) malignant tumor regrowth occurs locally, within 2 or 3 cm of the original boundary of the primary tumor site; 2) radiation therapy is a proven treatment for controlling the growth of the malignant tumor; and 3) there is a radiation dose-response relationship for the malignant tumor, but the dose that can be given safely with conventional external beam radiotherapy is limited by the tolerance or normal tissue. In brachytherapy, radiation doses are highest in close proximity to the radiotherapeutic source, providing a high tumor dose while sparing surrounding normal tissue. Interstitial brachytherapy is useful for treating malignant brain and breast tumors, among others.

Interstitial brachytherapy is traditionally carried out using radioactive seeds such as ^{125}I seeds. These seeds, however, produce inhomogeneous dose distributions. In order to achieve a minimum prescribed dosage throughout a target region of tissue, high activity seeds must be used, resulting in very high doses being delivered in some regions in proximity to the seed or seeds which can cause radionecrosis in healthy tissue.

Williams U.S. Pat. No. 5,429,582, entitled "Tumor Treatment," describes a method and apparatus for treating tissue surrounding a surgically excised tumor with radioactive emissions to kill any cancer cells that may be present in the tissue surrounding the excised tumor. In order to implement the radioactive emissions, Williams provides a catheter having an inflatable balloon at its distal end that defines a distensible reservoir. Following surgical removal of a tumor, the surgeon introduces the balloon catheter into the surgically created pocket left following removal of the tumor. The balloon is then inflated by injecting a fluid having one or more radionuclides into the distensible reservoir via a lumen in the catheter.

The apparatus described in Williams solves some of the problems found when using radioactive seeds for interstitial brachytherapy, but leaves some problems unresolved. The absorbed dose rate at a target point exterior to a radioactive source is inversely proportional to the square of the distance between the radiation source and the target point. As a result, where the radioactive source has sufficient activity to deliver a prescribed dose, say 2 centimeters into the target tissue, the tissue directly adjacent the wall of the distensible reservoir, where the distance to the radioactive source is very small, may still be overly "hot" to the point where healthy tissue necrosis may result. In general, the amount of radiation desired by the physician is a certain minimum amount that is delivered to a region up to about two centimeters away from the wall of the excised tumor. It is desirable to keep the radiation that is delivered to the tissue in the target treatment region within a narrow absorbed dose range to prevent over-exposure to tissue at or near the reservoir wall, while still delivering the minimum prescribed dose at the maximum prescribed distance from the reservoir wall.

There is still a need for an instrument which can be used to deliver radiation from a radioactive source to target tissue within the human body with a desired intensity and at a predetermined distance from the radiation source without over-exposure of body tissues disposed between the radiation source and the target.

SUMMARY OF THE INVENTION

The present invention solves the problems described above by providing an interstitial brachytherapy apparatus for delivering radioactive emissions to an internal body location. The apparatus includes a catheter body member having a proximal end and distal end, an inner spatial volume disposed proximate to the distal end of the catheter body member, an outer spatial volume defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume, and a radiation source disposed in the inner spatial volume. The inner and outer spatial volumes are configured to provide an absorbed dose within a predetermined range throughout a target tissue. The target tissue is located between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface. The predetermined dose range is defined as being between a minimum prescribed absorbed dose for delivering therapeutic effects to tissue that may include cancer cells, and a maximum prescribed absorbed dose above which healthy tissue necrosis may result.

In different embodiments, the inner spatial volume can be defined by a distensible polymeric wall containing radioactive source material which can be a fluid material, by a solid radioactive source, or by a region containing a plurality of solid radioactive sources. The outer spatial volume is defined by an expandable surface element that may be, for example, an inflatable polymeric wall or an expandable cage. The expandable surface element can cause tissue to conform to its intended shape, and preferably, the apparatus creates absorbed isodose profiles in the target tissue that are substantially similar in shape to the expandable surface element in substantially three dimensions.

The invention also provides a method for treating a proliferating tissue disease using interstitial brachytherapy at an internal body location. The method includes surgically creating access to the proliferating tissue within a patient and surgically resecting at least a portion of the proliferating tissue to create a resection cavity within body tissue. An interstitial brachytherapy apparatus for delivering radioactive emissions as described above is then provided and intra-operatively placed into the resection cavity. After a prescribed absorbed dose has been delivered to tissue surrounding the apparatus, the apparatus is removed. The radioactive source material may be placed into the interstitial brachytherapy apparatus after the apparatus is placed in the resection cavity, and may be removed before the apparatus is removed. The method has particular applications to brain and breast cancers.

DESCRIPTION OF THE DRAWINGS

The foregoing features, objects and advantages of the invention will become apparent to those skilled in the art from the following detailed description of a preferred embodiment, especially when considered in conjunction with the accompanying drawings in which:

FIG. **1** is a side view of an interstitial brachytherapy apparatus of the invention for delivering radioactive emissions to body tissue;

FIG. **2** is a cross-sectional view taken along the line **2**—**2** in FIG. **1**;

FIG. **3** is an additional embodiment of an interstitial brachytherapy apparatus of the invention having a solid radiation source;

FIG. **4** is an additional embodiment of an interstitial brachytherapy apparatus of the invention having a radiation source comprising a plurality of solid radiation particles;

FIG. **5** depicts a further embodiment of the invention wherein the inner and outer spatial volumes of the interstitial brachytherapy apparatus are non-spherical;

FIG. **6** illustrates an interstitial brachytherapy apparatus of the invention having an expandable outer spatial volume surface; and

FIGS. 7A–D illustrate the absorbed dose versus distance into target tissue for several interstitial brachytherapy apparatus configurations.

DESCRIPTION OF THE PREFERRED EMBODIMENT

A surgical instrument **10** for providing radiation treatment to proliferative tissue in a living patient is illustrated in FIG. **1**. Surgical instrument **10** includes a tubular body member **12** having first and second lumens **14** and **16** (FIG. **2**) extending from proximal ports **18** and **20** in a molded plastic hub **22** to inflation ports **24** and **26** formed through the side wall of the tube **12** and intersecting with the lumens **14** and **16**, respectively.

Affixed to the tubular body **12** proximate the distal end **28** thereof is an inner spatial volume **30** which may be defined by a generally spherical polymeric film wall **32**. The interior of the inner volume **30** is in fluid communication with the inflation port **26**. Surrounding inner spatial volume **30** is an outer spatial volume **34** defined by an outer polymeric film wall **36** that is appropriately spaced from the wall **32** of the inner spatial volume **30** when the two volumes are inflated or otherwise supported. Outer volume **34** encompasses inflation port **24**. With no limitation intended, the distensible polymeric film walls may comprise a biocompatible, radiation resistant polymer, such as silastic rubbers, polyurethanes, polyethylene, polypropylene, polyester, or PVC.

The embodiment of FIG. **1** includes inner and outer spatial volumes **30** and **34**, one inside the other. The outer spatial volume **34**, being the volume defined by the space between the inner spherical wall **32** and the outer spherical wall **36**, may be filled with air or, alternatively, a radiation absorbing fluid, such as a contrast media used in angiography. The inner volume **30** is then filled with a material containing a predetermined radionuclide, for example, I-125, I-131, Yb-169 or other source of radiation, such as radionuclides that emit photons, beta particles, gamma radiation, or other therapeutic rays. The radioactive material contained within the inner chamber **32** can be a fluid made from any solution of radionuclide(s), e.g., a solution of I-125 or I-131. A radioactive fluid can also be produced using a slurry of a suitable fluid containing small particles of solid radionuclides, such as Au-198, Y-90. Moreover, the radionuclide(s) can be embodied in a gel. One radioactive material useful in the invention is Iotrex™, a sterile single use, non-pyrogenic solution containing sodium 3-(^{125}I)iodo-4-hydroxybenzenesulfonate (^{125}I-HBS), available from Proxima Therapuetics, Inc. of Alpharetta, Ga.

As an alternative method of providing radioactive source material, such material may be coated on, chemically bonded to, or copolymerized with the material forming inner spherical wall **32**.

Where the radioactive source material is provided as a fluid or gel within inner spherical wall **32**, it may be desirable to provide a solid outer spherical wall **36**. Should inner spherical wall **32** rupture, the radioactive source material will be retained within outer spherical wall **36** and will not leak into the patient. For further safety, the burst strength of inner spherical wall **32** may be designed so as to be lower than that of outer spherical wall **36**. In this way, inner spherical wall **32** will rupture under stress first, releasing its contents into the larger combined space of the inner and outer volumes **30**, **34** and releasing any pressure built up within the inner spherical wall **32** and reducing the risk that radioactive material will spill into the patient. In the event of such a rupture, radioactive fluid could be drained from the apparatus through port **24** by way of lumen **14**, and also from port **26** by way of lumen **16**.

In a further embodiment, illustrated in FIG. **3**, instead of having the inner spatial volume **30** defined by a generally spherical polymeric film wall as at **32**, the catheter body member **12** may have a solid spherical radiation emitting material **44** as the inner spatial volume **30**. For example, radioactive micro spheres of the type available from the 3M Company of St. Paul, Minn., may be used. This radioactive source can either be preloaded into the catheter at the time of manufacture or loaded into the device after it has been implanted into the space formerly occupied by the excised tumor. The solid radiation emitting material **44** can be inserted through catheter **12** on a wire **46**, for example, using an afterloader (not shown). Such a solid radioactive core configuration offers an advantage in that it allows a wider range of radionuclides than if one is limited to liquids. Solid radionuclides that could be used with the delivery device of the present invention are currently generally available as brachytherapy radiation sources. In this embodiment solid spherical inner spatial volume **30** is surrounded by outer spherical wall **36**, defining outer spatial volume **34** between the outer spherical wall **36** and the inner spatial volume **30** with the outer spatial volume **34** occupied by a radioactive ray absorbent material, such as air, water or a contrast material.

In a further embodiment, illustrated in FIG. **4**, inner spatial volume **30**, instead of comprising a single solid sphere, may comprise a plurality of radiation emitting particles **44** strategically placed within the inner spatial volume **30** so as to radiate in all directions with a substantially equal intensity. This plurality of radiation emitting particles **44** can be mounted on the distal ends of a plurality of wires **46** that are routed through the catheter body **12** and exit a plurality of ports formed through the wall of the catheter body and reaching the lumen. This arrangement allows the exact positioning of the individual radiation sources **44** to be positioned so as to generate a desired resultant profile.

As illustrated in FIG. **5**, it is not essential to the invention that the volumes **30** and **34** have spherical walls, so long as the resultant dosing profile is consistent with the shape of the outer volume **34**. That is, the absorbed dose within the target tissue at points equidistant from the surface **36** of the outer spatial volume **34** should be substantially uniform in substantially every direction. Put another way, the three dimensional isodose profiles generated by the radiation source should be substantially similar in shape to the outer spatial volume **34**. Where the inner and outer spatial volumes are created by inflatable membranes and one of the volumes contains a fluid radiation source, this can be achieved by ensuring that the spacing between the wall of the inner volume and the wall of the outer volume remain generally constant. In either the concentric spherical embodiment of FIG. **1** or the non-spherical configuration of FIG. **5**, this result can be achieved by careful placement of precision blown or molded polymer partitions or by using compressible foams or mechanical spacers in the form of webs joining the inner wall **32** to the outer wall **36**. The desired isodose profiles conforming to the shape of the outer spatial volume **34** can also be obtained, for example, by strategic placement of a plurality of radioactive particle sources within the inner spatial volume **30**. Where the apparatus of the invention is deployed in soft tissue, it may also be important for the surface **36** of the outer spatial volume **34** to be sufficiently firm so as to force the target tissue to take on the shape of the surface **36** so that the desired relationship between the isodose profiles and the target tissue is achieved.

When used in an interstitial application, the surface of the outer spatial volume **34** must establish a relationship between the inner spatial volume **30** and the target tissue so as to achieve the aforementioned isodose profile, however, the surface of the outer volume need not be a solid material. For example, as illustrated in FIG. **6**, the surface of the outer volume **34** could be an expandable cage **48** formed from a shape memory metal, such as nitinol, or a suitable plastic, such as an expandable polyethylene cage. Such a cage can be formed in the desired shape to conform to a particular isodose profile, then be contracted for delivery to the target site in vivo, then expanded to cause the tissue surrounding the surgically resected region to take the appropriate shape. The size of the outer spatial volume **34** generally will correspond approximately to the amount of tissue resected, or be slightly larger, allowing the expandable surface of the outer spatial volume to urge tissue on the surface of the resected region into the appropriate shape to promote an even dose distribution around the outer spatial volume in the target tissue. In typical applications, the outer spatial volume has a diameter of approximately 2 to 4 centimeters. In these same applications, where the radiation source is provided as a fluid within an inner balloon, the inner balloon generally has a diameter of approximately 0.5 to 3 centimeters.

FIGS. **7**A–D illustrate the ability of an interstitial brachytherapy apparatus of the invention to deliver a minimum prescribed dose within target tissue while avoiding necrosis inducing radiation "hot spots" in tissue proximate to the apparatus. FIG. **7**A illustrates an interstitial brachytherapy apparatus (device A) such as those employed in U.S. Pat. No. 5,429,582, having a single spatial volume **50** filled with a radioactive material in solution. FIG. **7**B illustrates an interstitial brachytherapy apparatus (device B) of the invention having a first, inner spatial volume **30** filled with a radioactive material in solution and defined by membrane **32**, and a second, outer spatial volume **34** defined by membrane **36** that is substantially evenly spaced apart from membrane **32** in substantially three dimensions. FIG. **7**C illustrates an additional interstitial brachytherapy apparatus (device C) of the invention having a solid, spherical radiation source **44** as the inner spatial volume and a spherical outer spatial volume **34** defined by membrane **36**.

Each of the devices illustrated in FIGS. **7**A–C can be configured to deliver a substantially uniform dose at a given distance into the target tissue from the surface of the outer spatial volume **34** (or from single spatial volume **50** for device A) and to deliver a minimum prescribed dose within a given prescribed depth range into the tissue from the surface of the outer spatial volume **34**. However, the different devices provide very different dose profiles as a function of distance from the surface of the outer volume as illustrated in FIG. **7**D. FIG. **7**D plots the absorbed dose at a given distance into the target tissue from the surface of the outer spatial volume **34** for each of the devices A, B, and C.

Each device can deliver a minimum prescribed dose **52** at a given distance from the surface of the outer spatial volume. For example, device A can readily be configured to provide a dose in a therapeutic range, say between 40 to 60 Gray, at a distance between 0.5 and 1.0 cm from the outer spatial volume for an outer spatial volume having a diameter of 4.0 cm and being in contact with the resection cavity wall. In a typical embodiment, the radioactive source material ranges from approximately 150 to 450 mCi in activity and encompasses most of the target treatment area with a 0.4 to 0.6 Gray/hour isodose contour. At this treatment rate, treatment may be completed in approximately 3 to 7 days, or more commonly, in approximately 3 to 5 days.

In order to reach the minimum prescribed dosage at this distance, however, device A must provide a dose proximate to the surface of the outer spatial volume that is substantially larger than the minimum prescribed dose. For the 4.0 cm diameter outer spatial volume example, the absorbed dosage would be approximately 131 Gray at the outer spatial volume surface. Ideally, radiation therapy should make use the inherent difference in radiosensitivity between the tumor and the adjacent normal tissues to destroy cancerous tissue while causing minimal disruption to surrounding normal tissues. At high doses of radiation, however, the percentage of exposed cells that survive treatment decreases with first-order kinetics in proportion to increasing radiation dose. With increasing cell death comes increasing risk of necrosis or tissue death in healthy tissue that is treated with a high dose of radiation. Accordingly, it is desirable to keep the maximum radiation dose delivered by the brachytherapy apparatus as low as possible while still delivering the desired therapeutic dose to the desired range of tissue.

Comparing the plots A, B, and C, the absorbed dose profile in the space between the 2 cm site and the surface of the outer spatial volume for the devices of the invention is maintained in a much narrower range, preventing over-treatment of body tissue at or close to the surface of the outer volume of the device. Because devices B and C provide an outer spatial volume **34** between the radioactive source and

the target tissue, these devices can use hotter radiation sources to reach the minimum prescribed dosage, but take advantage of the distance between the radioactive source and the target tissue provided by the outer spatial volume **34** to reduce or eliminate hot spots in the target tissue.

Returning to the 4.0 cm diameter outer spatial volume example, if the radiation source is contained within an inner spatial volume, say a solid radioactive sphere such as device C, the absorbed dose profile becomes much different. If the radiation source is configured to provide the same 60 Gray dose at 0.5 cm into the target tissue, the absorbed dose at the outer spatial volume surface is only 94 Gray—a significant decrease from the 131 Gray dose for a type A device. In addition, the treatment range for the type C device will be extended under these circumstance as compared to the type A device, delivering a 40 Gray dose beyond 1.0 cm into the target tissue and delivering approximately double the dose at 3.0 cm into the target tissue. In one embodiment, the inner and outer spatial volumes are configured to control the absorbed dose at the outer spatial volume surface so that the absorbed dose is no greater than about 100 Gray while providing a therapeutic absorbed dose into the target tissue at the desired range. The capability of the apparatus of the invention to deliver absorbed doses deeper into the target tissue than prior interstitial brachytherapy devices while controlling the dose in proximity to the apparatus to reduce or eliminate the risk of healthy tissue necrosis allows for the use of brachytherapy in a greater number of cases.

The interstitial brachytherapy apparatus of the invention can be used in the treatment of a variety of malignant tumors, and is especially useful for in the treatment of brain and breast tumors.

Many breast cancer patients are candidates for breast conservation surgery, also known as lumpectomy, a procedure that is generally performed on early stage, smaller tumors. Breast conservation surgery is typically followed by postoperative radiation therapy. Studies report that 80% of breast cancer recurrences after conservation surgery occur near the original tumor site, strongly suggesting that a tumor bed "boost" of local radiation to administer a strong direct dose may be effective in killing any remaining cancer and preventing recurrence at the original site. Numerous studies and clinical trials have established equivalence of survival for appropriate patients treated with conservation surgery plus radiation therapy compared to mastectomy.

Surgery and radiation therapy are the standard treatments for malignant solid brain tumors. The goal of surgery is to remove as much of the tumor as possible without damaging vital brain tissue. The ability to remove the entire malignant tumor is limited by its tendency to infiltrate adjacent normal tissue. Partial removal reduces the amount of tumor to be treated by radiation therapy and, under some circumstances, helps to relieve symptoms by reducing pressure on the brain.

A method according to the invention for treating these and other malignancies begins by surgical resection of a tumor site to remove at least a portion of the cancerous tumor and create a resection cavity. Following tumor resection, but prior to closing the surgical site, the surgeon intraoperatively places an interstitial brachytherapy catheter apparatus, having an inner spatial volume and an outer spatial volume as described above but without having the radioactive source material loaded, into the tumor resection cavity. Once the patient has sufficiently recovered from the surgery, the interstitial brachytherapy catheter is loaded with a radiation source. The radioactive source dwells in the catheter until the prescribed dose of radiotherapy is delivered, typically for approximately a week or less. The radiation source is then retrieved and the catheter is removed. The radiation treatment may end upon removal of the brachytherapy apparatus, or the brachytherapy may be supplemented by further doses of radiation supplied externally.

It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. All references cited herein are expressly incorporated by reference in their entirety.

What is claimed is:

1. An interstitial brachytherapy apparatus for delivering radioactive emissions to an internal body location comprising:

(a) a catheter body member having a proximal end and distal end;

(b) an inner spatial volume disposed proximate to the distal end of the catheter body member;

(c) an outer spatial volume defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume; and

(d) a radiation source disposed in the inner spatial volume and generating a three-dimensional isodose profile that is substantially similar in shape to the expandable surface element.

2. The apparatus of claim **1**, wherein the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose for delivering therapeutic effects to a target tissue, the target tissue being defined between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface, the apparatus providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface.

3. The apparatus of claim **2**, wherein a predetermined spacing is provided between said inner spatial volume and the expandable surface element.

4. The apparatus of claim **3**, wherein the expandable surface element is adapted to contact tissue surrounding a resected cavity and adapted to conform the tissue to the desired shape of the expandable surface element.

5. The apparatus of claim **2**, wherein the minimum prescribed absorbed dose is 40 Gray at a distance of at least one centimeter from the expandable surface element.

6. The apparatus of claim **5**, wherein the dose rate in at least a portion of the target tissue is between about 0.4 and 0.6 Gray/hour.

7. The apparatus of claim **5**, wherein the maximum absorbed dose delivered to the target tissue is less than 100 Gray.

8. The apparatus of claim **2**, wherein the outer spatial volume has a diameter between about two and four centimeters.

9. The apparatus of claim **2**, wherein the inner spatial volume is an inner closed, distensible chamber defined by a further radiation transparent wall.

10. The apparatus of claim **9**, wherein the radioactive source is in a fluid form.

11. The apparatus of claim **10**, wherein the expandable surface element is a solid distensible surface and the outer spatial volume is a closed, distensible chamber and the expandable surface element is a radiation transparent wall.

12. The apparatus of claim 11, wherein a burst strength of the distensible chamber defining the outer spatial volume is greater than a burst strength of the chamber defining the inner spatial volume.

13. The apparatus of claim 1, wherein the expandable surface element is an expandable cage.

14. The apparatus of claim 13, wherein the expandable cage comprises a shape memory material.

15. The apparatus of claim 14, wherein the expandable cage comprises nitinol.

16. The apparatus of claim 1, wherein the radiation source is a solid radiation source.

17. The apparatus of claim 1, wherein the radiation source is a plurality of solid radiation sources arranged to provide an isodose profile having a shape substantially similar to the shape of the outer spatial volume.

18. The apparatus of claim 2, wherein the prescribed absorbed dose is delivered to the target tissue in substantially three dimensions.

19. A method for treating a proliferating tissue disease using interstitial brachytherapy at an internal body location comprising:

(a) surgically creating access to the proliferating tissue in a patient;

(b) surgically resecting at least a portion of the proliferating tissue to create a resection cavity within body tissue;

(c) providing an interstitial brachytherapy apparatus for delivering radioactive emissions comprising:

(i) a catheter body member having a proximal end and distal end;

(ii) an inner spatial volume disposed proximate to the distal end of the catheter body member;

(iii) an outer spatial volume defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume; and

(iv) a radiation source disposed in the inner spatial volume and generating a three-dimensional isodose profile that is substantially similar in shape to the expandable surface element;

(d) intraoperatively placing the interstitial brachytherapy apparatus into the resection cavity until a prescribed absorbed dose has been delivered to tissue surrounding the apparatus; and

(e) removing the interstitial brachytherapy apparatus.

20. The method of claim 19, further including placing the radioactive source into the interstitial brachytherapy apparatus after the step of placing the apparatus into the tumor resection cavity.

21. The method of claim 19, further including removing the radioactive source from the interstitial brachytherapy apparatus before the step of removing the apparatus.

22. The method of claim 19, wherein the proliferating tissue is a patient's brain.

23. The method of claim 19, wherein the proliferating tissue is a patient's breast.

24. The method of claim 19, further including configuring the inner and outer spatial volumes to provide a minimum prescribed absorbed dose for delivering therapeutic effects to a target tissue, the target tissue being defined between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface, the apparatus providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface.

25. The method of claim 24, further including providing a predetermined spacing between said inner spatial volume and the expandable surface element.

26. The method of claim 25, wherein the expandable surface element is adapted to contact tissue surrounding a resected cavity and adapted to conform the tissue to the desired shape of the expandable surface element.

27. The method of claim 24, wherein the minimum prescribed absorbed dose is 40 Gray at a distance of at least one centimeter from the expandable surface element.

28. The method of claim 27, wherein the dose rate in at least a portion of the target tissue is between about 0.4 and 0.6 Gray/hour.

29. The method of claim 27, wherein the maximum absorbed dose delivered to the target tissue is less than 100 Gray.

30. The method of claim 24, wherein the outer spatial volume has a diameter between about two and four centimeters.

31. The method of claim 24, wherein the step of configuring the inner and outer spatial volumes includes expanding the inner and outer spatial volumes.

32. A method for treating a proliferating tissue disease using interstitial brachytherapy at an internal body location comprising:

(a) surgically creating access to the proliferating tissue in a patient;

(b) surgically resecting at least a portion of the proliferating tissue to create a resection cavity within body tissue;

(c) providing an interstitial brachytherapy apparatus for delivering radioactive emissions comprising:

(i) a catheter body member having a proximal end and distal end;

(ii) an inner spatial volume disposed proximate to the distal end of the catheter body member;

(iii) an outer spatial volume defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume; and

(iv) a radiation source disposed in the inner spatial volume;

(d) intraoperatively placing the interstitial brachytherapy apparatus into the resection cavity;

(e) configuring the inner and outer spatial volumes to provide a minimum prescribed absorbed dose for delivering therapeutic effects to a target tissue, the target tissue being defined between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface, the apparatus providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface; and

(f) removing the interstitial brachytherapy apparatus.

33. The method of claim 32, wherein the step of configuring the inner and outer spatial volumes includes expanding the inner and outer spatial volumes.

34. A method for treating a proliferating tissue disease using interstitial brachytherapy at an internal body location comprising:

(a) surgically creating access to the proliferating tissue in a patient;

(b) surgically resecting at least a portion of the proliferating tissue to create a resection cavity within body tissue;

(c) providing an interstitial brachytherapy apparatus for delivering radioactive emissions comprising:

(i) a catheter body member having a proximal end and distal end;

(ii) an inner spatial volume disposed proximate to the distal end of the catheter body member;

(iii) an outer spatial volume defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume; and

(iv) a radiation source disposed in the inner spatial volume;

(d) intraoperatively placing the interstitial brachytherapy apparatus into the resection cavity;

(e) adapting the expandable surface element to contact tissue surrounding the resection cavity to conform the tissue to the desired shape of the expandable surface element;

(f) delivering a prescribed absorbed dose to tissue surrounding the apparatus; and

(g) removing the interstitial brachytherapy apparatus.

35. The method of claim **34**, wherein the step of adapting the expandable surface element includes expanding the outer surface volume.

36. An interstitial brachytherapy apparatus for delivering radioactive emissions to an internal body location comprising:

(a) a catheter body member having a proximal end and distal end;

(b) an inner spatial volume disposed proximate to the distal end of the catheter body member;

(c) an outer spatial volume defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume; and

(d) a radiation source disposed in the inner spatial volume;

wherein the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose for delivering therapeutic effects to a target tissue, the target tissue being defined between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface, the apparatus providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface.

* * * * *

Exhibit S

#3/Prior Art

~~EXPRESS MAILING LABEL NO:~~

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	Rance A. Winkler et al.
Application No.	:	09/293,524
Filed	:	April 15, 1999
Entitled	:	INTERSTITIAL BRACHYTHERAPY APPARATUS AND METHOD FOR TREATMENT OF PROLIFERATIVE TISSUE DISEASES
Docket No.	:	101360-15 (formerly ONE-008)

Group Art Unit: 3736

Examiner: Not Yet Assigned

Certificate of Mailing (37 C.F.R. 1.8(a))

I hereby certify that this correspondence is being deposited with the United States Postal Service Post Office as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on the date set forth below.

August 17, 1999 — Date of Signature and Mail Deposit

By: Ronald E. Cahill — Ronald E. Cahill, Reg. No: 38,403

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir:

Applicants hereby cite for the record in this application the enclosed documents listed on the attached copy of PTO Form 1449. The enclosed Information Disclosure Statement is

Application No.: 09/293,524
Filed: April 15, 1999
Group Art Unit No.: 3736

being filed prior to the mailing date of a first Office Action on the merits. Accordingly, Applicants believe that no fee or certification is required.

The Assistant Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 141449.

Respectfully submitted,

NUTTER, MCCLENNEN & FISH, LLP

Date: August 17, 1999

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Form PTO-1449 (Rev. 8-83)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO: 101360-15 (formerly ONB1168)

APPLICATION NO: 09/293,624

APPLICANT(S): Rance A. Winkler et al.

FILING DATE: April 15, 1999

GROUP ART UNIT: 3736

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE*
	AA	3 3 2 4 8 4 7	06/13/67	E.G. Zoumboulis	128 .	1.2	
	AB	3 8 7 2 8 5 6	03/25/75	Clayton	128	1.2	
	AC	4 4 1 7 5 7 6	11/29/83	Baran	128	207.15	
	AD	4 7 0 6 6 5 2	11/17/87	Horowitz	128	1.2	
	AE	4 7 5 4 7 4 5	07/05/88	Horowitz	128	1.2	
	AF	4 7 6 3 6 4 2	08/16/88	Horowitz	128	1.2	
	AG	4 8 2 1 7 2 5	04/18/89	Azam et al.	128	420 A	
	AH	4 8 6 7 7 4 1	09/19/89	Portnoy	604	10	
	AI	5 0 8 4 0 1 5	01/28/92	Moriuchi	604	96	
	AJ	5 1 0 6 3 6 0	04/21/92	Ishiwara et al.	600	2	
	AK	5 1 1 2 3 0 3	05/12/92	Pudenz et al.	604	49	
	AL	5 1 5 2 7 4 7	10/06/92	Olivier	604	93	
	AM	5 2 3 6 4 1 0	08/17/93	Gramov et al.	600	12	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	BA	2 1 0 5 2 0 1	23.03.83	United Kingdom	A61N	1/06	n/a	
	BB	0 3 4 0 8 8 1	08.11.89	EPO	A61N	5/10	n/a	
	BC	9 2 1 0 9 3 2	09.07.92	PCT	A61N	5/02	n/a	
	BD	9 3 0 9 7 2 4	27.05.93	PCT	A61B	17/36	n/a	

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)

	CA	Ashpole, R.D. et al., "A New Technique of Brachytherapy for Malignant Gliomas with Caesium-137: A New Method Utilizing a Remote Afterloading System," Clinical Oncology, vol. 2, 333-7 (1990);
Examiner		Date Considered: 6/15/00

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and considered. Include copy of this form with next communication to applicant.

#762442v1 -one-008 ids 1449.wpd

Form PTO-1449 (Rev. 8-83) — U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO: 101360-15 (formerly ONE-008)

APPLICATION NO: 09/293,524

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

APPLICANT(S): Rance A. Winkler et al.

FILING DATE: April 15, 1999

GROUP ART UNIT: 3736

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE*
	AN	5 4 2 9 5 8 2	07/04/95	Williams	600	2	
	AO	5 5 0 3 6 1 3	04/02/96	Weinberger	600	3	
	AP	5 6 1 1 7 6 7	03/18/97	Williams	600	2	
	AQ	5 6 6 2 5 8 0	09/02/97	Bradshaw et al.	600	3	
	AR	5 7 0 7 3 3 2	01/13/98	Weinberger	600	3	
	AS	5 7 1 3 8 2 8	02/03/98	Coniglione	600	7	
	AT	5 7 6 4 7 2 3	06/09/98	Weinberger et al.	378	65	
	AU	5 7 8 2 7 4 2	07/21/98	Crooker et al.	600	3	
	AV	5 7 8 5 6 8 8	07/28/98	Joshi et al.	604	141	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	BE	9 7 1 9 7 2 3	05.06.97	PCT	A61N	5/00	n/a	
	BF	9 8 1 2 9 7 9	02.04.98	PCT	A61B	19/00	n/a	

OTHER DOCUMENTS *(including Author, Title, Date, Pertinent Pages, Etc.)*

CB	Chun, M. et al., "Interstitial Iridium-192 Implantation for Malignant Brain Tumours. Part II: Clinical Experience," *The British Journal of Radiology*, vol. 62, 158-62 (1989);
CC	Garfield, J. et al., "Postoperative Intracavitary Chemotherapy of Malignant Gliomas," *J. Neurosurg.*, vol. 39, 315-22 (September 1973);
CD	Gutin, P. et al., "Brachytherapy of Recurrent Malignant Brain Tumors With Removable High-Activity Iodine-125 Sources," *J. Neurosurg.*, vol. 60, 61-8 (1984);
CE	Johannesen, T.B. et al., "Intracavity Fractionated Balloon Brachytherapy in Glioblastoma," *Acta Neurochir (Wien)*, vol. 141, 127-33 (1999);
Examiner	Date Considered:

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and considered. Include copy of this form with next communication to applicant. #762442v1 -one-008 ids 1449.wpd

Form PTO-1449 (Rev. 8-83)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO: 101360-15 (formerly ONE-008)	APPLICATION NO: 09/293,524
INFORMATION DISCLOSURE CITATION *(Use several sheets if necessary)*		APPLICANT(S): Rance A. Winkler et al.	
		FILING DATE: April 15, 1999	GROUP ART UNIT: 3736

		OTHER DOCUMENTS *(including Author, Title, Date, Pertinent Pages, Etc.)*
	CF	Leibel, S. et al., "The Integration of Interstitial Implantation Into the Preliminary Management of Patients With Malignant Gliomas: Results of a Phase II Northern California Oncology Group Trial," *Am. J. Clin. Oncol. (CCT)*, vol. 10, no. 2, p. 106 (1987);
	CG	Roberts, D. et al., "Interstitial Hyperthermia and Iridium Brachytherapy in Treatment of Malignant Glioma," *J. Neurosurg.*, vol. 64, 581-7 (1986);
	CH	Wu, A. et al., "Interstitial Iridium-192 Implantation for Malignant Brain Tumours. Part 1: Techniques of Dosimetry Planning," *The British Journal of Radiology*, vol. 62, 154-7 (1989).
Examiner		Date Considered: 6/15/00

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and considered. Include copy of this form with next communication to applicant.

Exhibit T

Clinical Oncology (1990) 2:333–337

Clinical Oncology

Original Article

A New Technique of Brachytherapy for Malignant Gliomas with Caesium-137: A New Method Utilizing a Remote Afterloading System*

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Abstract. Failure of conventional treatment to cure malignant gliomas has stimulated interest in various forms of brachytherapy. We describe a new method of using intracranial radiation utilizing a remotely-controlled afterloading system with a modified endotracheal tube as the applicator. The system used is the Selectron LDM/MDR (Nucleotron) which is a sophisticated machine widely available at radiotherapy centres and primarily used to treat gynaecological malignancies. It uses Caesium-137 in the form of spherical pellets in a linear source train within a sealed system. The applicator is implanted at the time of surgical resection. The inflated balloon stabilises the applicator and allows a suitable dose distribution at a distance from the source train to be achieved. Details of the implantation and radiation procedures as well as the dosimetry calculation are presented. The advantages are simplicity of use, the elimination of radiation risk to personnel and the combination of cytoreduction and applicator implantation in one surgical procedure.

Keywords: Malignant glioma; Brachytherapy; Caesium-137; Remote afterloading

INTRODUCTION

Conventional treatment does not cure malignant gliomas. Therapeutic failure is wholly attributable to the inability of surgery and external beam radiotherapy to locally eradicate tumour cells, with nine out of ten recurrences occurring within the margins of the original tumour (Hochberg and Pruitt, 1980).

Ionizing radiation is effective in prolonging survival (Salcman, 1980), with a linear correlation between radiation dose and length of survival (Walker *et al.*, 1979), but the limited tolerance of normal brain has restricted the maximum permissible dose to about 55–60 Gy (Leibel and Sheline, 1987). This has stimulated interest in different ways of increasing therapeutic effectiveness (Gutin *et al.*, 1984; Sewchand *et al.*, 1984; Murray *et al.*, 1986; Saleman *et al.*, 1986) including adjuvant modalities such as hyperthermia and radiosensitizers (Nelson *et al.*, 1986; Roberts *et al.*, 1986).

Caesium-137 has already been used to treat brain tumours in a stereotactically implanted and afterloaded applicator (Mantell *et al.*, 1986). We now describe a new form of brachytherapy utilizing Caesium-137 in a remote afterloading system with a modified endotracheal tube as the applicator. It can be used to irradiate the tumour bed following surgical resection of the tumour. It may be used alone or in combination with external beam irradiation. The advantages are simplicity of use, elimination of radiation risk to personnel and the avoidance of salvage craniotomy for mass effect caused by late radionecrosis as experienced in brachytherapy methods using wire implants. Only one surgical procedure is needed as the applicator is implanted under direct vision at the time of the cytoreductive operation.

* The authors wish to dedicate this paper to the late Dr Trevor Godden, Principal Physicist, Bristol Radiotherapy and Oncology Centre.

Correspondence and offprint requests to: Mr H. B. Coakham, Imperial Cancer Research Fund Paediatric and Neuro-Oncology Laboratory, Frenchay Hospital, Bristol BS16 1LE, UK.

In this pilot study, the feasibility of Caesium-137 brachytherapy was assessed in cases of malignant glioma that had relapsed following initial conventional therapy by surgery and external irradiation.

MATERIALS AND METHODS

Patient Selection

Patients were evaluated at a joint Neurosurgical/Oncological clinic. Criteria for inclusion were recurrent supratentorial malignant gliomas (Kernohan grade 3/4) where the tumours were judged to be accessible through a standard craniotomy on the evidence of CT and/or MRI scans. All these patients had full conventional therapy initially in the form of surgery and radiotherapy to a dose of 46-60 Gy given in five fractions per week over 4-6 weeks.

Apparatus

We used a remotely controlled afterloading system, the Selectron LDR/MDR (Nucletron). This is a 3–6 channel low/medium dose rate system installed as part of a purpose-built suite at the Radiotherapy Centre. Although it is mostly used for gynaecological cancers, no adaptation is necessary when treating gliomas.

The source container, transfer and control systems are all housed in the same unit from where the source train, which is made up of active and inactive spherical pellets, can be programmed to deliver the required dose. The radionuclide used is Caesium-137, contained in an active bead of 1.5 mm size and encapsulated in stainless steel to form a sphere with an outside diameter of 2.5 mm. These beads have a nominal activity of 1.4 GBq each.

The sources are pneumatically transferred into a standard selectron applicator (outside diameter 7.0 mm) which in turn fits snugly into the intracranial applicator that has been implanted surgically. This applicator is the only unusual piece of equipment and is an endotracheal tube (Portex, Blue Line, i.d. 8.0 with a Profile cuff) which has been shortened to 20 cm with the distal end sealed off just beyond the lower end of the balloon (Fig. 1).

Implantation Procedure

After routine investigation all patients underwent repeat craniotomy via the original osteoplastic flap.

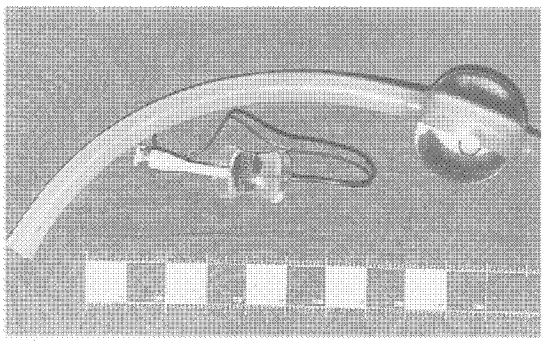

Fig. 1. The modified catheter with the sealed distal end and inflated balloon.

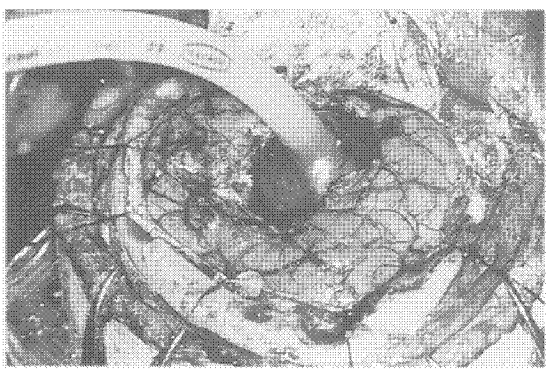

Fig. 2. The tumour cavity at operation with the modified catheter held in situ by the inflated balloon.

Cytoreduction remained the first aim and as much tumour was removed as deemed safe. The modified catheter was then inserted under direct vision so that the inflated balloon filled the postsurgical cavity, and the stem was brought out through one of the existing burr-holes (Fig. 2).

The balloon was filled with radio-opaque contrast medium (Conray 280 diluted to 2% strength with normal saline) to facilitate later X-ray visualization and dosimetry calculations. The volume to be used varies according to the size of the tumour bed, but a typical case needed 15 ml to give a balloon diameter of 2.9 cm. The scalp was closed tightly around the emerging tube and a padded head dressing applied. Routine antibiotic and steroid cover were given, consisting of Cefuroxime 1.5 g peroperatively and then 750 mg tds for three days, and Dexamethasone 4 mg tds and then reduced as and when possible.

The patient was then transferred to the Radiotherapy Centre for further treatment. No problems were encountered with this 'between hospital' transfer and patients tolerated it fairly well.

DOSIMETRY CALCULATION

After the patient had been transferred to the radiotherapy centre the 'Selectron' applicator was manually fitted into the protruding intracranial applicator, ensuring that the tip was right down to the base, and then marked on the outside to ensure accurate repositioning after the source localization procedure. A dummy source train was positioned in the applicator prior to taking localizing radiographs. These were AP and lateral skull radiographs incorporating the double ring method to determine magnification factor (Fig. 3).

The dose distribution is calculated from the above data on a Data General Eclipse computer system using in-house software. The plastic applicator and fluid in the balloon are soft tissue equivalent with regard to absorbed radiation dose and no additional factor is used in the dose calculation.

We aim to produce a mean dose rate of about 250 cGy/h at a distance of 0.5 cm from the balloon's surface for a total of about 20 h to give a total dosage of 50 Gy to the tumour bed. This is computed by varying the position of active and inactive beads in the source train until a satisfactory isodose curve to match the cavity shape is found (Fig. 3). In a typical case this is achieved by about a dozen active sources.

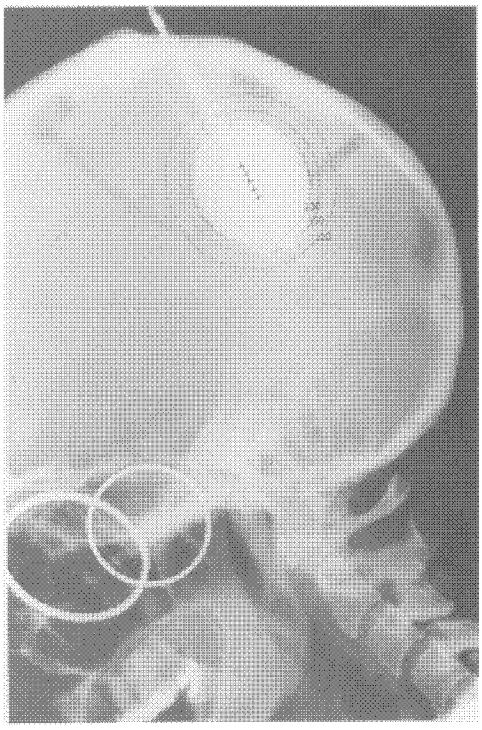

Fig. 3. Lateral radiograph showing the double ring method of magnification calculation, and Isodose curves computed around a dummy source train in the balloon.

RADIATION ADMINISTRATION PROCEDURE

This takes place in a purpose built suite comprising a private room for the patient with the Selectron equipment housed in an adjacent ante-room. The source delivery tubes pass through the wall and are fixed next to the patient's bed.

After removal of the dummy source train, the patient is connected to the machine via a treatment tube and the Selectron programmed to deliver the required dose. Treatment usually consisted of 3–4 hour periods with meal, visiting and overnight breaks as convenient, although the treatment was not divided into 'fractions' in the usual sense. Total treatment time varied from 15 to 20 hours and this could usually be completed within 48 hours.

Throughout the treatment periods the patients are attached to the machine and confined to bed (Fig. 4). In between these periods they are totally unrestrained and can carry out all activities of daily living. Nursing procedures continue in the normal way with

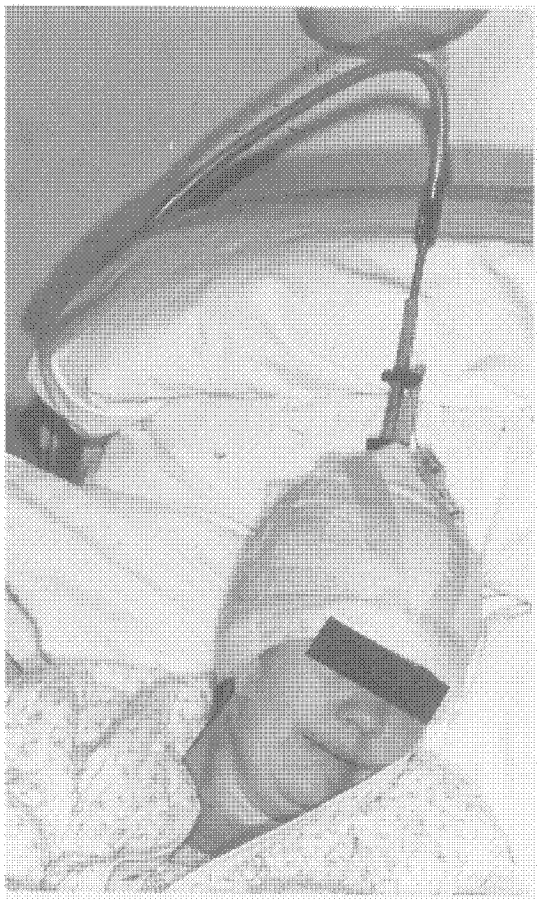

Fig. 4. A patient in bed attached to the machine while undergoing treatment.

a remote control unit at the door causing automatic source withdrawal when the room has to be entered.

At completion the balloon is deflated, the tube removed and the skin closed under local anaesthetic with strict asepsis. Patients seem to tolerate this procedure well and are usually discharged within a week.

DISCUSSION

Our approach is based on the belief that aggressive reduction in tumour volume offers the best form of palliation. Surgical debulking reduces the number of hypoxic cells and complements tumour bed irradiation as the next logical step. The technique of remotely controlled afterloading in brachytherapy is well established in other disciplines (Henschke *et al.*, 1964; Nori *et al.*, 1985; Mantell *et al.*, 1986; Hilaris *et al.*, 1987), but technical problems and availability of apparatus have limited its use in neurosurgery. It is advantageous as it not only eliminates radiation exposure to personnel, but allows flexibility of the treatment schedule and patient movements (Godden, 1988).

This method makes use of an advanced, purpose-built system which is readily available at radiotherapy centres. It could, therefore, be launched with the uncommon luxury of very limited additional expenditure and many of the initial problems associated with new approaches have been avoided.

Postimplantation adjustment of the radioactive sources becomes easy with the remote control and pneumatic transfer system of the Selectron machine and safe as it minimizes catheter manipulation. Migration of brachytherapy sources after implantation is a known problem in neurosurgery (Gutin and Dormandy, 1982) but this is largely overcome by microprocessor control in the Selectron system that guarantees constant accuracy of source positions to within 1mm.

Caesium-137, which emits both gamma and beta rays, was chosen because of the availability and convenience of the Selectron system. Its use is beneficial, however, since its long half-life of 30 years means a decay correction of only 2% per year while the unwanted beta rays can be absorbed by a relatively small thickness of stainless steel. A certain measure of dosimetrical versatility is possible in that the positions of the active beads can be changed to produce an isodose distribution specific to the geometry of the individual tumour beds.

We now deliver an absorbed dose of 50 Gy at 0.5 cm depth from the surface of the balloon. This is of the same order of magnitude as that used by others using stereotactically implanted sources (Gutin *et al.*, 1984) and takes into account the known tolerance of normal brain, the previously administered external beam radiotherapy and the remaining rim of tumour tissue. The dose at the surface of the balloon depends on the number and arrangement of sources as well as the balloon diameter and can be as high as 70 Gy.

The configuration of the balloon plays a key role in producing an acceptable dose distribution. The inverse square relationship between absorbed dose and distance from the source results in the larger the balloon diameter the greater the relative dose at prescribed distance from the balloon's surface. In practice it means that the balloon diameter should not be less than 2.5 cm in order to allow the depth dose at 0.5 cm from the surface to be greater than 50% of that at the surface. The balloon also acts as a buffer that absorbs the unacceptably high doses close to the sources and has a mechanical function in that it anchors the tube and acts as a stabilizer.

This system has been designed to irradiate the tumour bed locally. If therapeutic efficacy is shown in cases of relapse, the technique may then be used in primary therapy to give a high tumour-bed dose in association with external beam radiotherapy.

Interstitial irradiation with long-term implants has been used in glioma, but a major problem has been the high incidence of late radionecrosis necessitating further surgical intervention to decrease intracranial pressure (Gutin and Dormandy, 1982; Saleman *et al.*, 1986). This problem will be avoided by a removable catheter system such as ours, which is implanted into an already debulked tumour.

Patients seem to tolerate the procedure well. The introduction of infection remains a theoretical hazard, but removal of the applicator within 48 hours and appropriate antibiotic cover should reduce infective complications to a minimum. The size of the applicator makes it impractical to treat deep-seated gliomas in this way and as such represents its major limitation. There are other machines available, however, which use different sized applications which may enable this problem to be overcome in future.

We are evaluating this method on a prospective basis and the preliminary results will be reported elsewhere.

Acknowledgements. This project was supported by the Stanley Luff Trust Fund, c/o Frenchay Hospital, Bristol BS16 1LE. The authors wish to thank Dr Trevor Godden for his support and advice.

References

Godden TJ (1988). In *Physical Aspects of Brachytherapy*. Adam Hilger, Bristol, pp.212–214.

Gutin PH, Dormandy RH (1982). A coaxial catheter system for

afterloading radioactive sources for the interstitial irradiation of brain tumours. Technical note. *Journal of Neurosurgery*, **56**, 734–735.

Gutin PH, Phillips TL, Wara WM, Leibel SA, Hosobuchi Y, Levin VA, *et al.* (1984). Brachytherapy of recurrent malignant brain tumours with removable high activity iodine-125 sources. *Journal of Neurosurgery*, **60**, 61–68.

Gutin PH, Leibel SA, Wara WM, Choucair A, Levin VA, Phillips TL *et al.* (1987). Recurrent malignant gliomas: survival following interstitial brachytherapy with high-activity Iodine-125 sources. *Journal of Neurosurgery*, **67**, 864–873.

Henschke UK, Hilaris BS, Mahan GD (1964). Remote afterloading with intracavitary applicators. *Radiology*, **83**, 344–345.

Hilaris BS, Nori D, Anderson LL (1987). New approaches to brachytherapy. *Important Advances in Oncology*, 237–261.

Hochberg HF, Pruitt A (1980). Assumptions in the radiotherapy of glioblastoma. *Neurology*, **30**, 907–911.

Leibel SA, Sheline GE (1987). Tolerance of the central and peripheral nervous system to therapeutic irradiation. In *Advances in Radiation Biology*, eds Lett JT, Altmann KI, pp.257–258. Academic Press, New York.

Mantell BS, Klevenhagen SC, Afshar F (1986). An afterloaded applicator for the interstitial irradiation of brain tumours. *Clinical Radiology*, **37**, 35–38.

Murray KJ, Blumberg A. Strubler K, Sirota R, Altman J (1986). Permanent radioactive iodine seed implants following radical resection in recurrent human malignant astrocytomas. In *Biology of Brain Tumour*, eds Walker MD, Thomas DGT, pp.355–363. Martinus Nijhoff, Boston.

Nelson DF, Urtasun RC, Saunders WM, Gutin PH, Sheline GE (1986). Recent and current investigations of radiation therapy of malignant gliomas. *Seminars in Onchology*, **13**, 46–55.

Nori D, Hilaris BS, Chada M, Bains M, Jain S, Hopfan S *et al.* (1985). Clinical applications of a remote afterloader. *Endocurietherapy Hyperthermia and Oncology*, **1**, 193–200.

Roberts DW, Coughlin CT, Wong, TZ, Fratkin JD, Douple EB, Strohben JW (1986). Interstitial hyperthermia and brachytherapy in treatment of malignant glioma. A phase 1 clinical trial. *Journal of Neurosurgery*, **64**, 581–587.

Salcman M (1980). Survival in glioblastoma: historical perspective. *Neurosurgery*, **7**, 435–439.

Salcman M, Sewchand W, Amin PP, Bellis EH (1986). Technique and preliminary results of interstitial irradiation for primary brain tumours. *Journal of Neuro-oncology*, **4**, 141–149.

Sewchand W, Amin PP, Dryzmala RE, Salazar OM, Salcman M, Samaras GM *et al.* (1984). Removable high-intensity Iridium-192 brain implants. Technique and in vivo measurements in canine brain, *Journal of Neuro-oncology*, **2**, 177–185.

Walker MD, Strike TA, Sheline GE (1979). An analysis of dose-effect relationship in the radiotherapy of malignant gliomas. *International Journal of Radiation Oncology, Biology, Physics*, **5**, 1725–1731.

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Exhibit V

(12) **United States Patent**
Winkler et al.

(10) **Patent No.: US 6,482,142 B1**
(45) **Date of Patent: Nov. 19, 2002**

(54) **ASYMMETRIC RADIATION DOSING APPARATUS AND METHOD**

(75) Inventors: **Rance A. Winkler**, Atlanta; **Timothy J. Patrick**, Alpharetta, both of GA (US)

(73) Assignee: **Proxima Therapeutics, Inc.**, Alpharetta, GA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/464,727**

(22) Filed: **Dec. 16, 1999**

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/293,524, filed on Apr. 15, 1999, which is a continuation-in-part of application No. 08/900,021, filed on Jul. 24, 1997, now Pat. No. 5,913,813.

(51) **Int. Cl.**[7] **A61N 5/00**
(52) **U.S. Cl.** **600/3**
(58) **Field of Search** 600/1–8

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,706,652	A	11/1987	Horowitz	128/1.2
4,754,745	A	7/1988	Horowitz	128/1.2
5,422,926	A	6/1995	Smith et al.	378/121
5,562,594	A	10/1996	Weeks	600/3
5,724,400	A	3/1998	Swerdloff et al.	378/65
5,800,333	A	9/1998	Liprie	600/3
5,803,895	A	9/1998	Kronholz et al.	600/3
5,851,182	A	12/1998	Sahadevan	600/407
5,863,284	A	1/1999	Klein	600/3

FOREIGN PATENT DOCUMENTS

WO	WO 97/19723	6/1997	A61N/5/00

OTHER PUBLICATIONS

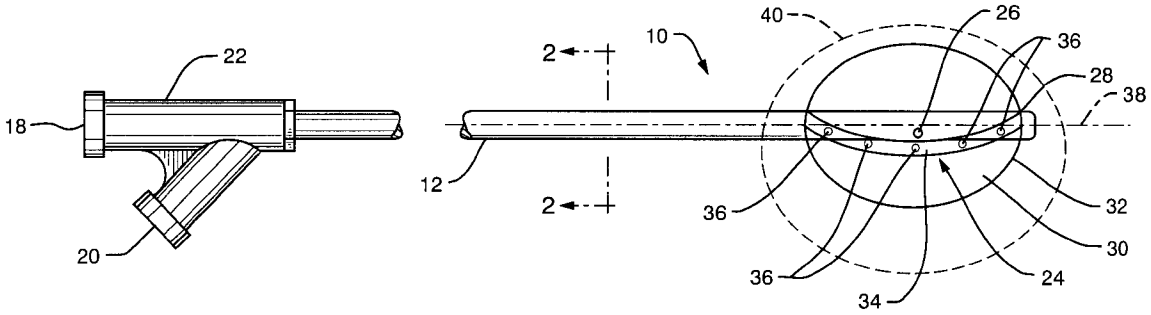
Ravinder, Nath, Ph.D. et al., Development of an ^{241} Am Applicator For Intracavitary Irradiation of Gynecologic Cancers, I.J. Radiation Oncology, Biology, Physics, May 1988, vol. 14, No. 5, pp. 969–978.

Primary Examiner—John P. Lacyk
(74) *Attorney, Agent, or Firm*—Thomas J. Engellenner; Ronald E. Cahill; Nutter McClennen & Fish LLP

(57) **ABSTRACT**

An interstitial brachytherapy apparatus of the invention delivers radioactive emissions in an asymmetric fashion to target tissue surrounding a surgical extraction site. The apparatus includes an expandable outer surface element defining an apparatus spatial volume, a radiation source disposed within the apparatus volume, and a means for providing predetermined asymmetric isodose curves within the target tissue. In one configuration, asymmetric isodose curves are created in the target tissue by shaping or locating the radiation source so as to be asymmetrically placed with respect to a longitudinal axis of the apparatus. In other configurations, asymmetric radiopaque shielding is provided between the radiation source and the target tissue. A surgical procedure using the apparatus is also described.

14 Claims, 4 Drawing Sheets



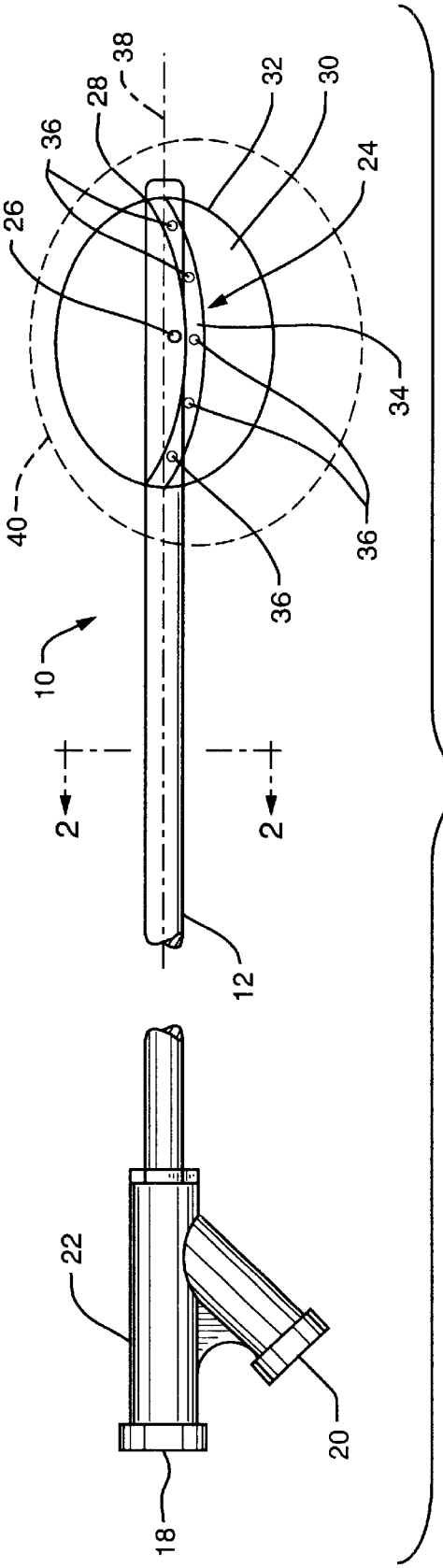


FIG. 1

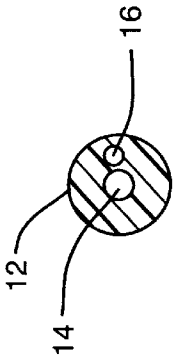


FIG. 2

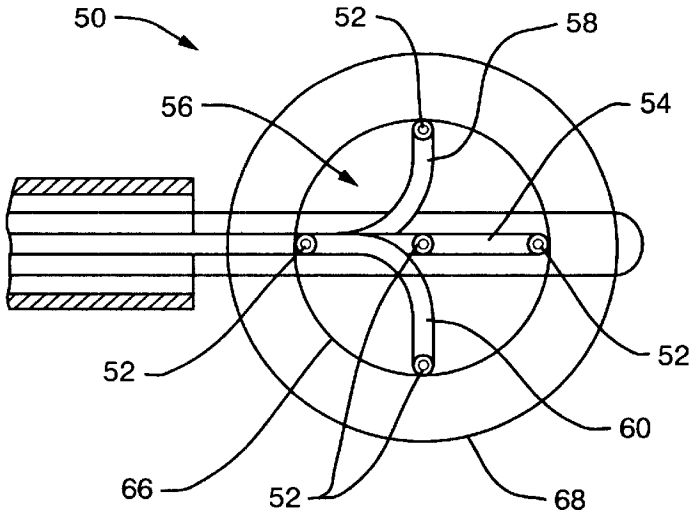


FIG. 3

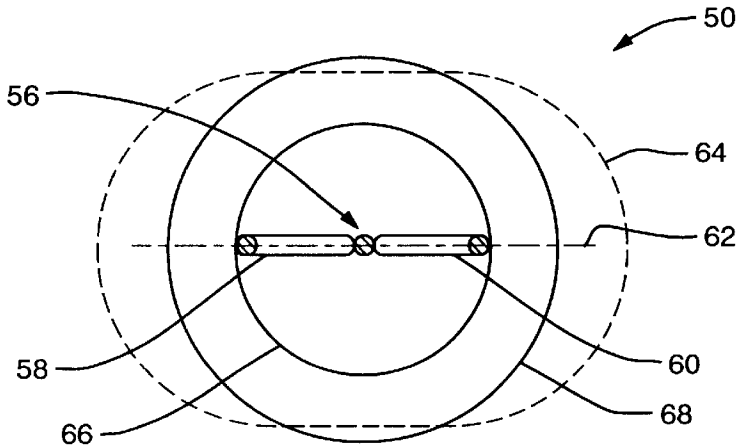


FIG. 3A

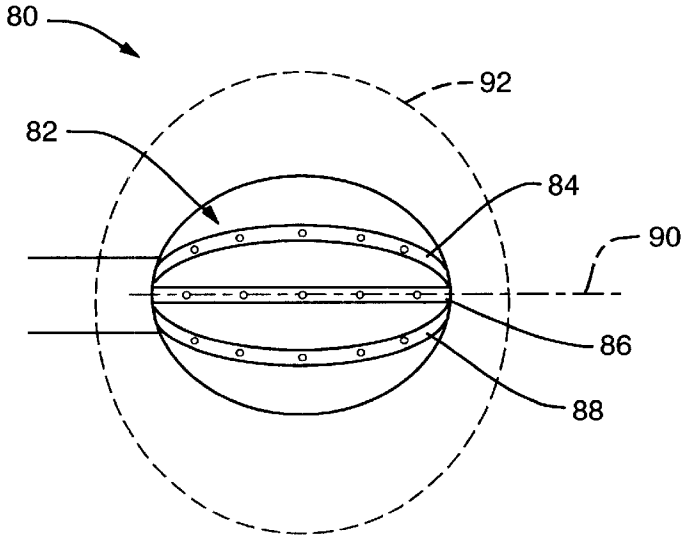


FIG. 4

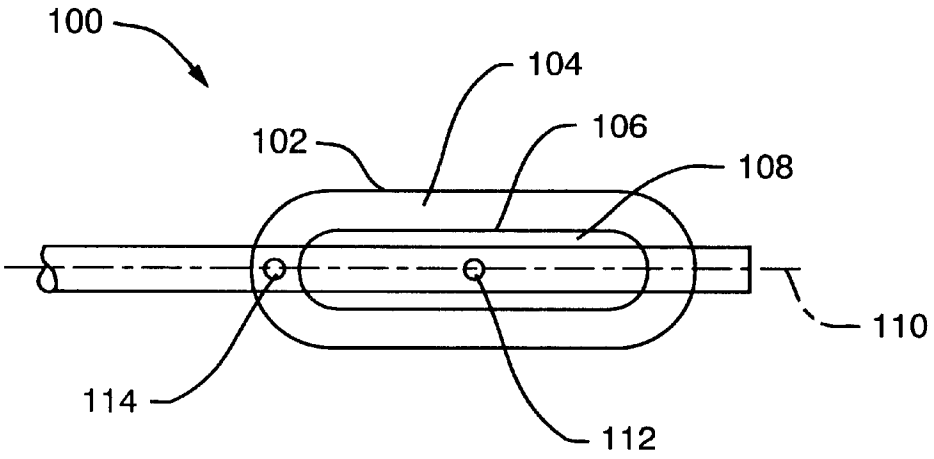

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FIG. 5

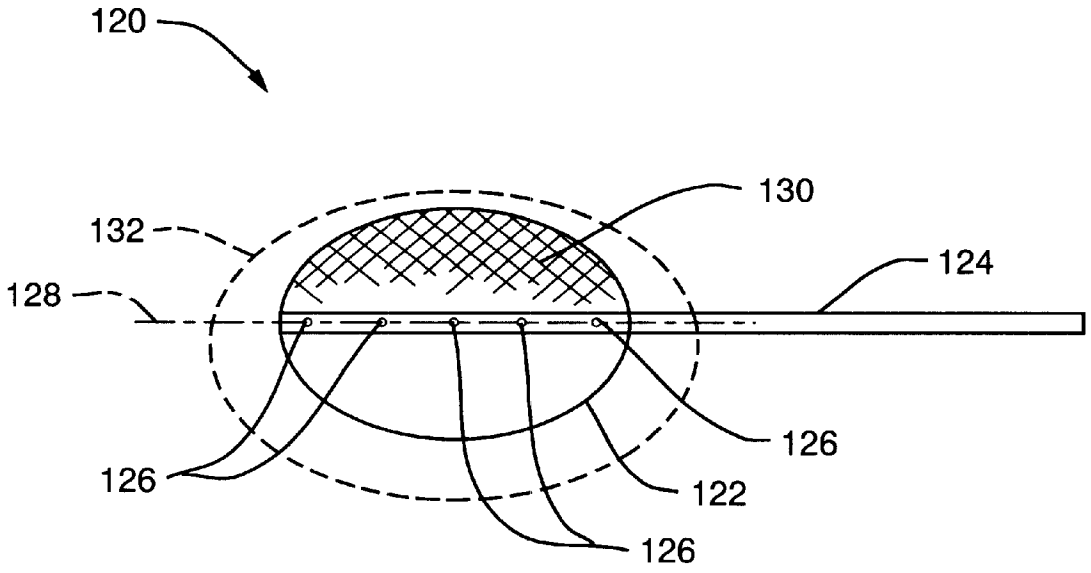
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FIG. 6

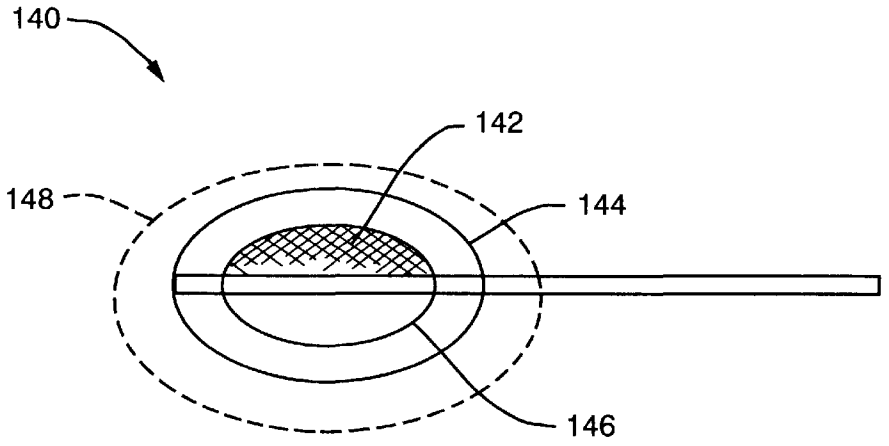

FIG. 7

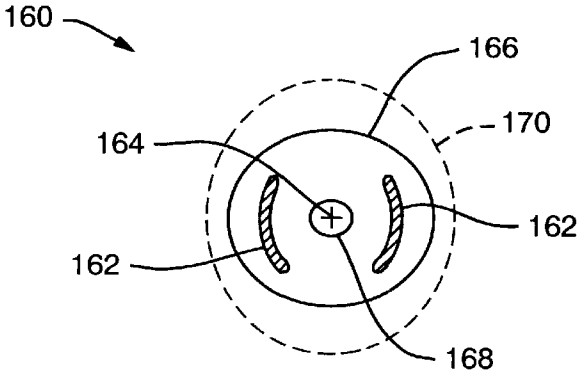

FIG. 8

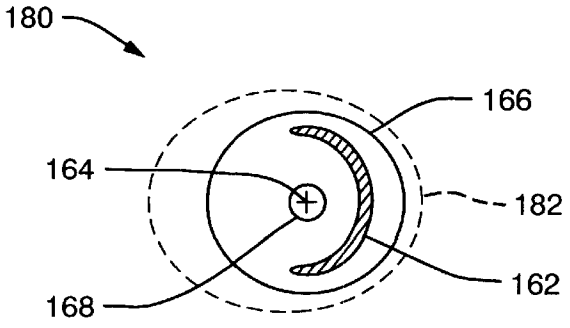

FIG. 9

ASYMMETRIC RADIATION DOSING APPARATUS AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of co-pending U.S. patent application Ser. No. 09/293,524, filed Apr. 15, 1999, pending which is a continuation-in-part U.S. patent application Ser. No. 08/900,021, filed Jul. 24, 1997 (now issued as U.S. Pat. No. 5,913,813 to Williams et al.); the contents of these applications are specifically incorporated herein by reference.

BACKGROUND OF THE INVENTION

The, invention relates generally to an apparatus for use in treating proliferative tissue disorders, and more particularly to an apparatus for the treatment of such disorders in the body by the application of radiation.

Malignant tumors are often treated by surgical resection of the tumor to remove as much of the tumor as possible. Infiltration of the tumor cells into normal tissue surrounding the tumor, however, can limit the therapeutic value of surgical resection because the, infiltration can be difficult or impossible to treat surgically. Radiation therapy can be used to supplement surgical resection by targeting the residual tumor margin after resection, with the goal of reducing its size or stabilizing it. Radiation therapy can be administered through one of several methods, or a combination of methods, including external-beam radiation, stereotactic radiosurgery, and permanent or temporary interstitial brachytherapy. The term "brachytherapy," as used herein, refers to radiation therapy delivered by a spatially confined radioactive material inserted into the body at or near a tumor or other proliferative tissue disease site. Owing to the proximity of the radiation source, brachytherapy offers the advantage of delivering a more localized dose to the target tissue region.

For example, brachytherapy is performed by implanting radiation sources directly into the tissue to be treated. Brachytherapy is most appropriate where 1) malignant tumor regrowth occurs locally, within 2 or 3 cm of the original boundary of the primary tumor site; 2) radiation therapy is a proven treatment for controlling the growth of the malignant tumor; and 3) there is a radiation dose-response relationship for the malignant tumor, but the dose that can be given safely with conventional external beam radiotherapy is limited by the tolerance or normal tissue. In brachytherapy, radiation doses are highest in close proximity to the radiotherapeutic source, providing a high tumor dose while sparing surrounding normal tissue. Interstitial brachytherapy is useful for treating malignant brain and breast tumors, among others.

Interstitial brachytherapy is traditionally carried out using radioactive seeds such as ^{125}I seeds. These seeds, however, produce inhomogeneous dose distributions. In order to achieve a minimum prescribed dosage throughout a target region of tissue, high activity seeds must be used, resulting in very high doses being delivered in some regions in proximity to the seed or seeds which can cause radionecrosis in healthy tissue. One attempt to address this problem, at least with respect to limiting dosages to critical organs near the radioactive seed site, has been to provide a shield directly on a portion of the seed or on an applicator that holds the seed to shield the particularly sensitive tissue. (E.g., Nath et al., Development of an ^{241}Am Applicator for Intracavitary Irradiation of Gynecologic Cancers, *Intl. J. Radiation Oncology Biol. Phys.*, Vol., 14, pp. 969–978.) While this approach may be appropriate for some applications, it may still be overly "hot" for treating proximate tissue on the unshielded side of the seed, while not providing an effective dose on the shielded side of the seed.

Williams U.S. Pat. No. 5,429,582, entitled "Tumor Treatment," describes a method and apparatus for treating tissue surrounding a surgically excised tumor with radioactive emissions to kill any cancer cells that may be present in the tissue surrounding the excised tumor. In order to implement the radioactive emissions, Williams provides a catheter having an inflatable balloon at its distal end that defines a distensible reservoir. Following surgical removal of a tumor, the surgeon introduces the balloon catheter into the surgically created pocket left following removal of the tumor. The balloon is then inflated by injecting a fluid having one or more radionuclides into the distensible reservoir via a lumen in the catheter.

The apparatus described in Williams solves some of the problems found when using radioactive seeds for interstitial brachytherapy, but leaves some problems unresolved. The absorbed dose rate at a target point exterior to a radioactive source is inversely proportional to the square of the distance between the radiation source and the target point. s a result, where the radioactive source has sufficient activity to deliver a prescribed dose, say 2 centimeters into the target tissue, the tissue directly adjacent the wall of the distensible reservoir, where the distance to the radioactive source is very small, may still be overly "hot" to the point where healthy tissue necrosis may result. In general, the amount of radiation desired by the physician is a certain minimum amount that is delivered to a region up to about two centimeters away from the wall of the excised tumor. It is desirable to keep the radiation that is delivered to the tissue in the target treatment region within a narrow absorbed dose range to prevent over-exposure to tissue at or near the reservoir wall, while still delivering the minimum prescribed dose at the maximum prescribed distance from the reservoir wall. It is also desirable, at least in some applications, to provide these advantages while tailoring the radiation dosage to avoid fully dosing sensitive tissue or to reduce the amount of radiation that escapes the patient's body.

There its still a need for an instrument which can be used to deliver radiation from a radioactive source to target tissue within the human body with a desired intensity and at a predetermined distance from the radiation source without over-exposure of body tissues disposed between the radiation source and the target, and with the ability to shape the radiation dose to protect sensitive tissue or to protect against radiation exposure outside of the patient's body which may affect healthcare providers or others who might come close to the patient.

SUMMARY OF THE INVENTION

The present invention solves the problems described above by providing an interstitial brachytherapy apparatus for delivering radioactive emissions in an asymmnetric fashion to target tissue surrounding a surgical extraction site. The apparatus includes an expandable outer surface element defining an apparatus spatial volume, a radiation source disposed within the apparatus volume, and a means for providing predetermined asymmnetric isodose profile within the target tissue.

In one configuration, asymmetric isodose curves are created in the target tissue by shaping or locating the radiation source so as to be asymmetrically placed with respect to a

longitudinal axis of the apparatus. In one example of an apparatus having this configuration, an inner volume containing a liquid radioisotope is asymmetrically placed within the apparatus volume so as to result in an isodose profile in the target tissue that is asymmetric about the longitudinal axis of the apparatus.

In another example, the radiation source comprises a plurality of spaced apart solid radioactive particles disposed within the apparatus volume and arranged to provide a predetermined asymmetric isodose curve within the target tissue. In one particular example, the plurality of spaced apart radioactive particles are provided on a single elongate member that is shaped so that some of the radioactive particles are farther from the longitudinal axis of the apparatus than others. In other particular examples, a plurality of members carrying radioactive particles are provided with at least one of the members being shaped so as to place at least one radioactive particle asymmetrically with respect to the longitudinal axis of the apparatus.

An interstitial brachytherapy apparatus of the invention may also be implemented in a device having an expandable outer surface defining an apparatus volume, a radiation source disposed within and spaced apart from the expandable outer surface, and at least one asymmnetric radiation shield spaced apart from the radiation source, the asymmetric radiation shielding resulting in predetermined asymmetric isodose curves with in the target tissue. In one embodiment, radiopaque shielding is provided on a portion of the expandable outer surface. In another embodiment, the radiation source is encompassed within a second, inner surface within the apparatus volume, with radiopaque shielding provided on at least a portion of the inner surface. In still further embodiments, one or more radiation shields are spaced apart from the radiation source and within the apparatus volume to achieve the desired asymmetric isodose distribution within the target tissue.

The invention also provides a method for treating a proliferating tissue disease using interstitial brachytherapy at an internal body location. The method includes surgically creating access to the proliferating tissue within a patient and surgically resecting at least a portion of the proliferating tissue to create a resection cavity within body tissue. An interstitial brachytherapy apparatus for delivering radioactive emissions as described above is then provided and intra-operatively placed into the resection cavity. After a prescribed absorbed dose has been delivered to tissue surrounding the apparatus, the apparatus is removed. The radioactive source material may be placed into the interstitial brachytherapy apparatus after the apparatus is placed in the resection cavity, and may be removed before the apparatus is removed. The method has particular applications to brain and breast cancers.

DESCRIPTION OF THE DRAWINGS

The foregoing features, objects and advantages of the invention will become apparent to those skilled in the art from the following detailed description of a preferred embodiment, especially when considered in conjunction with the accompanying drawings in which:

FIG. **1** is a side view of an interstitial brachytherapy apparatus of the invention for delivering asymmetric radioactive doses to body tissue;

FIG. **2** is a cross-sectional view taken along the line **2**—**2** in FIG. **1**;

FIG. **3** is a side view of an additional embodiment of an interstitial brachytherapy apparatus of the invention;

FIG. **3**A is an end view of the interstitial brachytherapy apparatus of FIG. **3**;

FIG. **4** is a side view of an additional embodiment of an interstitial brachytherapy apparatus of the invention;

FIG. **5** is a side view of an interstitial brachytherapy apparatus of the invention configured for use with a liquid radiation source.

FIG. **6** is a side view of an interstitial brachytherapy device of the invention employing radiopaque coatings;

FIG. **7** is a side view of an interstitial brachytherapy device of the invention employing radiopaque coating and a liquid radiation source; and

FIGS. **8** and **9** are end views of interstitial brachytherapy devices of the invention employing radiopaque shields.

DESCRIPTION OF THE PREFERRED EMBODIMENT

A surgical instrument **10** for providing radiation treatment to proliferative tissue in a living patient is illustrated in FIG. **1**. Surgical instrument **10** includes a tubular body member **12** having first and second lumens **14** and **16** (FIG. **2**) extending from proximal ports **18** and **20** in a molded hub **22**. The first lumen **14** carries a radioactive source **24** and second lumen **16** communicates with inflation port **26** formed through the side wall of the tube **12**.

Affixed to the tubular body **12** proximate the distal end **28** thereof is an outer spatial volume **30** defined by an outer polymeric film barrier **32** that is appropriately spaced from the radioactive source **24**. Outer volume **30** encompasses inflation port **26**. With no limitation intended, the distensible polymeric film walls may comprise a biocompatible, radiation resistant polymer, such as silastic rubbers, polyurethanes, polyethylene, polypropylene, polyester, or PVC. The outer spatial volume **30** may be filled with air, saline or, alternatively, a radiation absorbing fluid, such as a contrast media used in angiography. Alternatively, the surface of outer volume **30** need not be a solid material. For example the surface of the outer volume **30** could be an expandable cage formed from a shape memory metal, such as nitinol, or a suitable plastic, such as an expandable polyethylene cage. Such a cage can be formed in the desired shape to conform to a particular isodose profile, contracted for delivery to the target site in vivo, then expanded to cause the tissue surrounding the surgically resected region to take the appropriate shape. The size of the outer spatial volume **30** generally will correspond approximately to the amount of tissue resected. For some applications, the size of the outer spatial volume **30** may be slightly smaller than the resected volume while for other applications, the outer spatial volume will be slightly larger than the resected volume, allowing the expandable surface of the outer spatial volume to urge tissue on the surface of the resected region into the appropriate shape to promote an even dose distribution around the outer spatial volume in the target tissue. In typical applications, the outer spatial volume has a diameter of approximately 2 to 6 centimeters.

Radiation source **24** comprises a wire **34** having one or more solid radioactive particles **36** located on the wire **34**. For example, radioactive micro spheres of the type available from the 3M Company of St. Paul, Minn., may be used as the solid radioactive particles. Such a solid radioactive particle configuration offers an advantage in that it allows a wider range of radionuclides than if one is limited to liquids. Solid radionuclides that could be used with the delivery device of the present invention are currently generally available as brachytherapy radiation sources. Examples of

radioactive materials which can be selected by a person of ordinary skills in the art for use with the present invention may be found in Tables 1 to 4 of PCT Publication WO 97/19723, which is hereby incorporated by reference.

The, radioactive source **24** can either be preloaded into the catheter at the time of manufacture, or loaded into the device after it has been implanted into the space formerly occupied by the excised tumor. If loaded after implantation, the solid radiation emitting material **36** can be inserted through lumen **14** on a wire **34**, for example using an afterloader (not shown).

Radiation source **24** has an asymmetric configuration with respect to a longitudinal axis **38** of the instrument **10**. That is, radiation source **24** is shaped so as to result in an isodose profile **40** that varies radially about the longitudinal axis **38**. More simply, the isodose profile **40** of FIG. **1** has a shorter radius from the longitudinal axis **38** on the top side of the instrument **10** as shown in FIG. **1** than on the bottom side. The asymmetrically shaped isodose curve **40** may be created by providing a plurality of solid radioactive particles **36** on a curved wire **34** in a spaced apart relationship. This configuration will result in certain of the solid radioactive particles **36** being farther from the longitudinal axis **38** of the instrument **10** than others, and will result in the illustrated asymmetric isodose profile **40**. One way to provide the illustrated radioactive source **24** configuration is to form wire **34** from a solid or tubular shape memory alloy such as nickel-titanium alloys known in the art to have such properties. Wire **34** can then be preformed to the desired shape, can be compressed into a substantially straight configuration to pass through lumen **14**, and will resume its desired shape once inside volume **30** where wire **34** will be free from steric constraints imposed inside the lumen **14**. The resulting asymmetric isodose curve **40** can be further tailored by using solid radioactive particles **36** having differing specific activities to achieve the desired dosing.

In,one embodiment, volume **30** and barrier **32** act to separate target tissue from the radiation source **24**. Ideally, radiation therapy should make use the inherent difference in radiosensitivity between the tumor and the adjacent normal tissues to destroy cancerous tissue while causing minimal disruption to surrounding normal tissues. At high doses of radiation, however, the percentage of exposed cells that survive treatment decreases with first-order kinetics in proportion to increasing radiation dose. With increasing cell death comes increasing risk of necrosis or tissue death in healthy tissue that is treated with a high dose of radiation. Accordingly, it is desirable to keep the maximum radiation dose delivered by the brachytherapy apparatus as low as possible while still delivering the desired therapeutic dose to the desired range of tissue. One method for achieving this result is to provide a "hotter" radiation source in a spaced apart relationship to the target tissue. In this way, because the intensity of the radiation emitted by a source drops with the square of the distance from the source, the effective dosage may be maintained below necrosis levels in target tissue closest to the interstitial brachytherapy apparatus while providing the required dosage to a greater depth into the target tissue. (See, e.g., U.S. Pat. No. 5,913,813 which is hereby incorporated by reference in its entirety.) The capability of the apparatus of the invention to deliver absorbed doses deeper into the target tissue than prior interstitial brachytherapy devices while controlling the dose in proximity to the apparatus to reduce or eliminate the risk of healthy tissue necrosis allows for the use of brachytherapy in a greater number of cases.

For example, it is desirable to provide an interstitial brachytherapy device configured to provide a dose in a therapeutic range, say between 40 to 60 Gray, at a distance between 0.5 and 1.0 cm from the outer spatial volume for an outer spatial volume having a diameter of 4.0 cm and being in contact with the resection cavity wall. In a typical embodiment, the radioactive source material ranges from approximately 150 to 450 mCi in activity and encompasses most of the target treatment area with a 0.4 to 0.6 Gray/hour isodose contour. At this treatment rate, treatment may be completed in approximately 3 to 7 days, or more commonly, in approximately 3 to 5 days.

In some applications, the desired dosing profile is consistent with the shape of the outer volume **30**. That is, the absorbed dose within the target tissue at points equidistant from the surface **32** of the outer spatial volume **30** should be substantially uniform in substantially every direction. Put another way, the three dimensional isodose profiles generated by the radiation source should be substantially similar in shape to the outer spatial volume **30**. Where the apparatus of the invention is deployed in soft tissue, it may also be important for the surface **32** of the outer spatial volume **30** to be sufficiently firm so as to force the target tissue to take on the shape of the surface **30** so that the desired relationship between the isodose profiles and the target tissue is achieved

While the interstitial brachytherapy device **10** of FIG. **1** may employ these techniques to positive effect, this device specifically alters the isodose profile for applications where particularly sensitive tissue or other concerns result in a desire to limit the dosage on one or more sides of the device as illustrated by isodose curve **40**.

In a further embodiment of the brachytherapy device **50** of the invention, illustrated in FIG. **3**, three solid radiation particles **52** are provided in a linear portion **54** of radiation source **56**, while two additional radiation particles **52** are provided on co-planar extending portions **58**, **60** of radiation source **56**. An end view of the device **50** of FIG. **3** is shown in FIG. **3**A with extending portions **58**, **60** provided in a single plane **62**, and resulting in isodose profile **64**. A second inner, expandable surface **66** can also be provided within outer surface **68**; the inner surface **66** enclosing the entirety of radiation source **56**.

By providing extending portions **58**, **60** having radioactive particles in the indicated co-planar relationship, areas of reduced dosage can be created on opposed sides of the device while maintaining symmetric dosing in all other directions. Of course, the number of sources and their configuration can be changed to create a desired asymmetric dosage. For example, an additional source could be added, for example above plane **62**, to result in a symmetric isodose profile in all directions except the direction below the plane **62** which would have a lower dosage.

An additional device **80** of the invention, shown in FIG. **4**, includes a radiation source **82** that is made up of three wires **84**, **86**, **88**, each having a plurality of solid radiation particles. Wire **86** is a straight wire extending along the longitudinal axis **90** of the device, while wires **84**, **88** each curve as wire **34** described above with respect to FIG. **1**. Wires **84**, **88** are coplanar, resulting in an isodose profile **92** that is similar to isodose profile **64** of FIG. **3**A. That is, the isodose profile will be symmetric in the plane in which the wires **84**, **88** are disposed, but will have areas of reduced dosage in directions transverse to that plane (i.e., in FIG. **4**, in the directions into and out of the page). As with the device **50** of FIGS. **3** and **3**A, device **80** can be configured with more or fewer wires **84**, **86**, **88**, and can be provided in configurations other than the depicted co-planar configuration in order to achieve desired asymmetric isodose profiles.

The asymmetric dosing effect achieved by the devices described above can also be achieved using a liquid radiation source. For example, device **100**, illustrated in FIG. **5**, has an outer surface **102** defining an outer volume **104** and an inner surface **106** defining an inner volume **108**. The inner surface **106** is asymmetrically shaped or located with respect to the longitudinal axis **110** of the device **100** so as to result in the desired asymmetric dosing when the inner volume **108** is filled with a radioactive fluid. The inner volume **108** is spaced apart from the outer surface **102** and can be filled with a material containing a predetermined radionuclide, for example, I-125, I-131, Yb-169 or other source of radiation, such as radionuclides that emit photons, beta particles, gamma radiation, or other therapeutic rays. The radioactive material contained within the inner volume **108** can be a fluid made from any solution of radionuclide(s), e.g., a solution of Ir-192, I-125 or I-131. A radioactive fluid can also be produced using a slurry of a suitable fluid containing small particles of solid radionuclides, such as Au-198, Y-90. Moreover, the radionuclide(s) can be embodied in a gel. One radioactive material useful in the invention is Iotrex™, a sterile single use, non-pyrogenic solution containing sodium 3-(^{125}I)iodo-4-hydroxybenzenesulfonate (^{125}I-HIBS), available from Proxima Therapeutics, Inc. of Alpharetta, Ga. The inner volume **108** may be filled with radioactive fluid through port **112**. Similarly, outer volume **104** can be filled on inflated using port **114**.

A desired asymmetric dosing profile having the dosing characteristics described above may also be created by using asymmetric shielding between the radiation source and the target tissue as illustrated in FIGS. **6** through **9**. In the device **120** of FIG. **6**, a balloon **122** is located on the distal end of catheter **124**. Radioactive particles **126** are disposed along the longitudinal axis **128** of the device. A portion of the surface, either inner or outer, of balloon **122** is coated with a radiopaque material **130** to result in asymmetric isodose curve **132**. Radiopaque materials suitable for coating onto a polymeric surface of balloon **122** include, for example, barium, tungsten, bismuth, tantalum and tin.

A further device **140** having radiopaque shielding **142** is illustrated in FIG. **7**. Device **140** includes an outer volume surface **144** and an inner volume surface **146**. Inner surface **146** may contain a liquid radiation source, or may enclose one or more solid particles as used in device **120** (FIG. **6**). In device **140**, the radiopaque material **142** is coated onto a portion of either the inner or outer side of the inner volume surface **146**, resulting in a desired asymmetric isodose profile **148**.

Additional devices **160**, **180** of the invention having radiation shielding **162** are illustrated in FIGS. **8** and **9**, respectively. In these devices **160**, **180**, one or more radiation shields **162** are provided between and spaced apart from a radiation source (not shown) located along a longitudinal axis **164** of the device and the target tissue, which will be located outside of expandable surface **166**. The radiation source can include a liquid or a solid radiation source as described above. Shields **162** can be formed from radiopaque materials including those described above with respect to the radiopaque coating and can extend longitudinally from a base on the device located within the expandable surface **166**.

As shown in FIG. **8**, device **160** has two radiation shields **162** on opposed sides of catheter **168**. This configuration results in lower radiation dosing on the two sides of the device **160** on which the shields **162** are located as shown by isodose curve **170**. Device **180** (FIG. **9**) has a single radiation shield **162** resulting in an asymmetric isodose curve **182** as shown. A person or ordinary skill in the art will recognize that other configurations may be employed to achieve desired isodose curves.

The interstitial brachytherapy apparatus of the invention can be used in the treatment of a variety of malignant tumors, and is especially useful for in the treatment of brain and breast tumors.

Many breast cancer patients are candidates for breast conservation surgery, also known as lumpectomy, a procedure that is generally performed on early stage, smaller tumors. Breast conservation surgery is typically followed by postoperative radiation therapy Studies report that 80% of breast cancer recurrences after conservation surgery occur near the original tumor site, strongly suggesting that a tumor bed "boost" of local radiation to administer a strong direct dose may be effective in killing any remaining cancer and preventing recurrence at the original site. The apparatus described herein can be used for either the primary or boost therapy. Numerous studies and clinical trials have established equivalence of survival for appropriate patients treated with conservation surgery plus radiation therapy compared to mastectomy.

Surgery and radiation therapy are also the standard treatments for malignant solid brain tumors. The goal of surgery is to remove as much of the tumor as possible without damaging vital brain tissue. The ability to remove the entire malignant tumor is limited by its tendency to infiltrate adjacent normal tissue. Partial removal reduces the amount of tumor to be treated by radiation therapy and, under some circumstances, helps to relieve symptoms by reducing pressure on the brain.

A method according to the invention for treating these and other malignancies begins by surgical resection of a tumor site to remove at least a portion of the cancerous tumor and create a resection cavity. Following tumor resection, but prior to closing the surgical site, the surgeon intraoperatively places an interstitial brachytherapy catheter apparatus, having an inner spatial volume and an outer spatial volume as described above but without having the radioactive source material loaded, into the tumor resection cavity. Once the patient has sufficiently recovered from the surgery, the interstitial brachytherapy catheter is loaded with a radiation source. The radioactive source dwells in the catheter until the prescribed dose of radiotherapy is delivered, typically for approximately a week or less. The radiation source is then retrieved and the catheter is removed. The radiation treatment may end upon removal of the brachytherapy apparatus, or the brachytherapy may be supplemented by further doses of radiation supplied externally.

It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention, including, but not limited to, combinations of elements from different embodiments found herein. All references cited herein are expressly incorporated by reference in their entirety.

What is claimed is:

1. An interstitial brachytherapy apparatus for treating target tissue surrounding a surgical extraction comprising:

an expandable outer surface defining a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated;

a radiation source disposed completely within the expandable outer surface and located so as to be spaced apart from the apparatus volume, the radiation source further being asymmetrically located and arranged within the expandable surface to provide predetermined asymmetric isodose curves with respect to the apparatus volume.

2. A surgical apparatus for providing radiation treatment to target tissue comprising:

an expandable outer surface defining an apparatus volume;

a radiation source replaceably disposable within the expandable outer surface, the radiation source comprising a plurality of solid radiation sources arranged to provide predetermined asymmetric isodose curves within the target tissue, the plurality of solid radiation sources being provided in a spaced apart relationship on a single elongate member, the single elongate member being shaped to provide asymmetric placement of the spaced apart solid radiation sources with respect to a longitudinal axis through the apparatus volume.

3. The apparatus of claim **2**, further comprising a catheter in communication with the apparatus volume, the elongate member extending through the catheter into the apparatus volume.

4. The apparatus of claim **3**, wherein the elongate member is formed of a shape memory alloy, the elongate member being shaped to provide asymmetric placement of the spaced apart solid radiation sources, taking on a substantially straight shape while being inserted through the catheter to the apparatus volume, and resuming an asymmetric shape when extended into the apparatus volume.

5. A surgical apparatus for providing radiation treatment to target tissue comprising:

an expandable outer surface defining an apparatus volume;

a radiation source replaceably disposable within the expandable outer surface, the radiation source comprising a plurality of solid radiation sources arranged to provide predetermined asymmetric isodose curves within the target tissue, wherein at least one of the plurality of solid radiation sources has a different specific activity from at least one other solid radiation source.

6. A surgical apparatus for providing radiation treatment to target tissue comprising:

an expandable outer surface defining an apparatus volume;

a radiation source replaceably disposable within the expandable outer surface, the radiation source comprising a plurality of solid radiation sources arranged to provide predetermined asymmetric isodose curves within the target tissue, the plurality of radiation sources being provided on at least two elongate members extending into the apparatus volume, at least one of the elongate members being shaped to provide asymmetric placement of a radiation source with respect to a longitudinal axis through the apparatus volume.

7. The apparatus of claim **6**, wherein each of the at least two elongate members includes a plurality of solid radiation sources provided in a spaced apart relationship.

8. The apparatus of claim **1**, wherein the expandable outer surface is sufficiently rigid to deform the target tissue into the shape of the expandable outer surface, causing the predetermined asymmetric isodose curves to penetrate into the target tissue to a prescribed depth.

9. An interstitial brachytherapy apparatus for treating target tissue surrounding a surgical extraction comprising:

an expandable outer surface having a base and defining a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated;

a radiation source disposed completely within and spaced apart from the expandable outer surface; and

an asymmetric radiation shield spaced apart from the radiation source, the asymmetric radiation shield providing predetermined asymmetric isodose curves with respect to the apparatus volume.

10. The apparatus of claim **9**, wherein the asymmetric radiation shield comprises a radio-opaque material disposed on only a portion of the expandable outer surface.

11. The apparatus of claim **10**, wherein the expandable outer surface comprises an inflatable balloon.

12. The apparatus of claim **11**, wherein the radiation shield comprises a barium material disposed a portion of the inflatable balloon.

13. The apparatus of claim **9**, further comprising at least one radiation shield extending from the base of the expandable outer surface toward an opposite end of the expandable surface, the shield being in between and spaced apart from the radiation source and the expandable outer surface, the shield forming a radio-opaque barrier between a portion of the radiation source and the target tissue.

14. The apparatus of claim **13**, wherein the radiation shield comprises two shields provided on opposite sides of the radiation source.

* * * * *

Exhibit PP

#6/Amend. A
J.A.

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COPY OF PAPERS ORIGINALLY FILED

Docket No.: 101360-16
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Rance A. Winkler, et al.

Application No.: 09/464,727-7988

Group Art Unit: 3736

Filed: December 16, 1999

Examiner: J. Lacyk

For: ASYMMETRIC RADIATION DOSING APPARATUS AND METHOD

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on the date shown below.
Dated: 2/27/02 Signature: [signature] (Ronald E. Cahill)

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AMENDMENT

Commissioner for Patents
Washington, DC 20231

Dear Sir:

In response to the Office Action dated October 31, 2001 (Paper No. 5), please amend the above-identified U.S. patent application by replacing all of the claims with the Clean Copy of All Pending Claims below. A Complete Set of Pending Claims With Markings to Show Amendments Made is attached to this Amendment following the signature page.

03/14/2002 SSITHIB1 00000039 09464727
02 FC:202 84.00 OP

03/14/2002 SSITHIB1 00000039 09464727
02 FC:202 84.00 OP

Application No.: 09/464,727-7988 Docket No.: 101360-16

Clean Copy of All Pending Claims

1. (Amended) An interstitial brachytherapy apparatus for treating target tissue surrounding a surgical extraction comprising:

an expandable outer surface defining a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated;

a radiation source disposed completely within the expandable outer surface and located so as to be spaced apart from the apparatus volume, the radiation source further being asymmetrically located and arranged within the expandable surface to provide predetermined asymmetric isodose curves with respect to the apparatus volume.

2. (Amended) A surgical apparatus for providing radiation treatment to target tissue comprising:

an expandable outer surface defining an apparatus volume;

a radiation source replaceably disposable within the expandable outer surface, the radiation source comprising a plurality of solid radiation sources arranged to provide predetermined asymmetric isodose curves within the target tissue, the plurality of solid radiation sources being provided in a spaced apart relationship on a single elongate member, the single elongate member being shaped to provide asymmetric placement of the spaced apart solid radiation sources with respect to a longitudinal axis through the apparatus volume.

3. The apparatus of claim 2, further comprising a catheter in communication with the apparatus volume, the elongate member extending through the catheter into the apparatus volume.

4. The apparatus of claim 3, wherein the elongate member is formed of a shape memory alloy, the elongate member being shaped to provide asymmetric placement of the spaced apart solid radiation sources, taking on a substantially straight shape while being inserted through the catheter to the apparatus volume, and resuming an asymmetric shape when extended into the apparatus volume.

2 1.6

5. (Amended) A surgical apparatus for providing radiation treatment to target tissue comprising:

an expandable outer surface defining an apparatus volume;

a radiation source replaceably disposable within the expandable outer surface, the radiation source comprising a plurality of solid radiation sources arranged to provide predetermined asymmetric isodose curves within the target tissue, wherein at least one of the plurality of solid radiation sources has a different specific activity from at least one other solid radiation source.

6. (Amended) A surgical apparatus for providing radiation treatment to target tissue comprising:

an expandable outer surface defining an apparatus volume;

a radiation source replaceably disposable within the expandable outer surface, the radiation source comprising a plurality of solid radiation sources arranged to provide predetermined asymmetric isodose curves within the target tissue, the plurality of radiation sources being provided on at least two elongate members extending into the apparatus volume, at least one of the elongate members being shaped to provide asymmetric placement of a radiation source with respect to a longitudinal axis through the apparatus volume.

7. The apparatus of claim 6, wherein each of the at least two elongate members includes a plurality of solid radiation sources provided in a spaced apart relationship.

8. The apparatus of claim 1, wherein the expandable outer surface is sufficiently rigid to deform the target tissue into the shape of the expandable outer surface, causing the predetermined asymmetric isodose curves to penetrate into the target tissue to a prescribed depth.

9. (Amended) An interstitial brachytherapy apparatus for treating target tissue surrounding a surgical extraction comprising:

an expandable outer surface having a base and defining a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated;

17

a radiation source disposed completely within and spaced apart from the expandable outer surface; and

an asymmetric radiation shield spaced apart from the radiation source, the asymmetric radiation shield providing predetermined asymmetric isodose curves with respect to the apparatus volume.

10. (Amended) The apparatus of claim 9, wherein the asymmetric radiation shield comprises a radio-opaque material disposed on only a portion of the expandable outer surface.

11. The apparatus of claim 10, wherein the expandable outer surface comprises an inflatable balloon.

12. The apparatus of claim 11, wherein the radiation shield comprises a barium material disposed a portion of the inflatable balloon.

13. The apparatus of claim 9, further comprising at least one radiation shield extending from the base of the expandable outer surface toward an opposite end of the expandable surface, the shield being in between and spaced apart from the radiation source and the expandable outer surface, the shield forming a radio-opaque barrier between a portion of the radiation source and the target tissue.

14. The apparatus of claim 13, wherein the radiation shield comprises two shields provided on opposite sides of the radiation source.

15. Canceled.

16. Canceled.

17. Canceled.

18. Canceled.

19. Canceled.

REMARKS/ARGUMENTS

Applicants appreciate the Examiner's indication that claims 2 through 7 define allowable subject matter. Applicants have amended claims 2, 5 and 6 to be independent claims including the recitations of the base claim and any intervening claims and to correct any rejections under 35 U.S.C. § 112, second paragraph. Applicants have also amended the preamble to read that the recited apparatus is a surgical apparatus for providing radiation treatment to target tissue. This amendment is supported in the opening paragraph of the Detailed Description of the Invention.

Applicants have amended independent claim 1 (from which claim 8 depends) and independent claim 9 (from which claims 10 to 14 depend, directly or ultimately) to better define the invention. Applicants have also amended claim 10 to recite that radio-opaque material is disposed *only* on a portion of the expandable surface. Applicants cancel claims 15 to 19 herein. Accordingly, claims 1 to 14 are now pending.

Claim Rejections Over McGrath

Claims 1 and 9 stand rejected as anticipated by McGrath (US 6,036,631) under 35 U.S.C. § 102(e). In particular, the Examiner states that "McGrath et al discloses a device for treating tissue having an expandable outer surface and a radiation source disposed within the expandable surface having a plurality of solid radiation sources (Fig. 2B). McGrath et al also teaches the use of shielding to absorb some of the radiation."

McGrath is directed to a device and method for treatment of cancerous tissue from a body conduit, i.e., interluminal treatment. By contrast, Applicants' apparatus is an interstitial brachytherapy apparatus, used to treat remaining proliferative tissue surrounding a surgical extraction site such as might be found in the treatment of brain or breast cancers. As a result of this difference in purpose, there are a number of key differences in structure between McGrath and claims 1 and 9.

For example, the expandable outer surface of claims 1 and 9 defines a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated. (See Page 7, lines 8 to 15.) Further, the radiation source is disposed completely within the expandable surface and is spaced apart from the apparatus volume. (See Page 8, line 23 to page 9 line 13, noting the

advantages of providing the radiation source within the interstitial volume and spaced apart from the target tissue; See also each of FIGS. 1 and 3 through 9, showing the radiation sources disposed entirely within the expandable surface). Further with respect to claim 1, the radiation source is located and arranged within the expandable outer surface so as to create asymmetric radiation isodose curves with respect to the apparatus volume. (See Page 9, line 23 to page 10, line 7.) That is, the radiation source is arranged within the device so that asymmetric dosing appears at the apparatus volume, which is configured to correspond to the interstitial void created by surgical extraction of diseased tissue.

The device of McGrath is not configured for use interstitially, it is configured for use interluminally, with balloons provided only to hold its catheter within a lumen, or to dialate the lumen. Accordingly, the radiation source in McGrath is not located completely within any of the disclosed balloons, nor is it located and arranged to provide an asymmetric dose at an apparatus volume that conforms to an interstitial void. Rather, McGrath provides an x-ray tube 48 that slides within a catheter, or a plurality of radiation-emitting seeds 52 "essentially forming a linear source." (Column 5, lines 34 to 37.) Accordingly, McGrath lacks several of the features recited in claim 1.

McGrath also lacks the features recited in claim 8 which depends from claim 1. Claim 8 recites that the expandable outer surface is sufficiently rigid to deform the target tissue into the shape of the expandable outer surface, causing the predetermined asymmetric isodose curves to penetrate into the target tissue to a prescribed depth. That is, the expandable outer surface actually causes the interstitial void to take on the same shape as the apparatus volume so that, even for oddly shaped voids in soft tissue, the shape of the target tissue that is to receive the asymmetric radiation dose will be the same as for the apparatus volume, enabling precise delivery of prescription doses of radiation asymmetrically from Applicants' claimed configuration.

As described above, McGrath does not disclose, teach or suggest the configuration that is recited in claim 9 that is also recited in claim 1. In addition to the structure it recites in common with claim 1, claim 9 recites an asymmetric radiation shield spaced apart from the radiation source, the asymmetric radiation shield providing predetermined asymmetric isodose curves with

respect to the apparatus volume. No portion of McGrath provides an outer expandable surface defining such an apparatus volume, and, while other configurations are referred to generically, the shielding that is provided by McGrath is simply a tubular shield that protects the bladder neck and sphincter. (See, Column 10, lines 7 to 39.) Nowhere does McGrath disclose, teach or suggest providing asymmetric shielding spaced apart from a radiation source so as to create predetermined asymmetric isodose curves with respect to an apparatus volume defined by the outer expandable surface.

Claim Rejections Over Ciezki in view of Apple

Claims 1 and 8 to 14 stand rejected as unpatentable over Ciezki (EP 0 867 200) in view of Apple (WO 99/33515) under 35 U.S.C. § 103. In particular, the Examiner states that:

> Ciezki et al teaches a treatment device having a plurality of radiation sources disposed in a catheter. Ciezki et al also teaches the use of shielding or an attennator made from a radio-opaque material i.e. tantalum. Ciezki et al teaches the claimed device except for the use of an inflatable balloon catheter or the specific use of barium as the shielding material. Apple et al teaches a radioactive treatment device that uses an inflatable balloon to place the catheter at the treatment site. . . . Therefore a modification of Ciezki et al such that the catheter includes an inflatable balloon would have been obvious to help in the placement and retention of the catheter at the treatment site;

The combination of Ciezki and Apple suffers from all of the same problems as McGrath does. Regarding claim 1, the Examiner recognizes that Ciezki does not provide an expandable outer surface defining a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated; and a radiation source disposed completely within the expandable outer surface and located so as to be spaced apart from the apparatus volume. Apple does not fill in this missing teaching. Apple is directed to a catheter apparatus that is filled with a radioactive gas. The catheter can be used to treat restenosis after angioplasty, or it can treat malignancies. The "restenosis" configuration includes a number of balloons of the type generally used to hold a catheter in an artery; that is, interlumenally. None of these balloons define an apparatus volume within an interstitial void within which the radioactive source is completely placed. Even where Apple discloses a device for interstitial use (See, e.g., FIGS. 17 to 19), the radiation source completely fills the balloon and is not in a spaced apart relationship from the balloon as is recited in claim 1. Thus, even if a balloon from Apple were added to Ciezki, the configuration of claim

1 would not result.

More significantly, neither Apple nor Ciezki nor their combination teaches asymmetric placement of a radiation source that is completely within an expandable surface defining an apparatus volume so as to result in asymmetric radiation isodose curves with respect to the apparatus volume. As described above and in the portions of the application cited above, Applicants' configuration provides significant advantages in the treatment of marginal proliferative tissue surrounding an interstitial void left by a surgical tumor resection. Accordingly, neither Ciezki nor Apple nor their combination renders the subject matter of claim 1 unpatentable to Applicants. Claim 8, which depends from claim 1, is further patentable over Ciezki and Apple because neither teaches or suggests the recitations of claim 8 for the same reasons as described above with respect to McGrath.

As described above, neither Ciezki nor Apple nor their combination discloses, teaches or suggests the configuration that is recited in claim 9 that is also recited in claim 1 – that is, an expandable outer surface having a base and defining a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated; and a radiation source disposed completely within and spaced apart from the expandable outer surface.

In addition to the structure it recites in common with claim 1, claim 9 recites an asymmetric radiation shield spaced apart from the radiation source, the asymmetric radiation shield providing predetermined asymmetric isodose curves with respect to the apparatus volume. No portion of Ciezki defines such an apparatus volume and the only embodiment of Apple that provides an apparatus volume (FIGS 17 to 19) does not include any shielding. Where Ciezki and Apple do provide shielding, it is to protect blood flowing through the apparatus as it irradiates an aterial wall. The disclosed shielding does not provide asymmetric radiation dosing with respect to an expandable outer surface defining an apparatus volume, because there is no such volume in these references. As described above and in the portions of the application cited above, Applicants' configuration with asymmetric shielding provides significant advantages in that it provides precise delivery of prescription doses of radiation asymmetrically about an interstitial void created by surgical resection of diseased tissue. Neither of these references, alone or

combined, teach or suggest a device that achieves this result.

Conclusion

For all of the foregoing reasons, Applicants request that the Examiner reconsider the application and allow each of claims 1 to 14 to issue. If the Examiner believes that an interview would facilitate the resolution of any outstanding issues, the Examiner is kindly requested to contact the undersigned.

Dated: 2/27/02

Respectfully submitted,

By

Ronald E. Cahill
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Complete Set of Pending Claims With Markings to Show Amendments Made

1. An interstitial brachytherapy apparatus for treating target tissue surrounding a surgical extraction comprising:

an expandable outer surface defining [an] a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated;

a radiation source [replaceably disposable] disposed completely within the expandable outer surface and located so as to be spaced apart from the apparatus volume, the radiation source [comprising a plurality of solid radiation sources arranged] further being asymmetrically located and arranged within the expandable surface to provide predetermined asymmetric isodose curves [within the target tissue] with respect to the apparatus volume.

2. [The apparatus of claim 1, wherein a] A surgical apparatus for providing radiation treatment to target tissue comprising:

an expandable outer surface defining an apparatus volume;

a radiation source replaceably disposable within the expandable outer surface, the radiation source comprising a plurality of solid radiation sources arranged to provide predetermined asymmetric isodose curves within the target tissue, the plurality of solid radiation sources [are] being provided in a spaced apart relationship on a single elongate member, the single elongate member being shaped to provide asymmetric placement of the spaced apart solid radiation sources with respect to a longitudinal axis through the apparatus volume.

3. The apparatus of claim 2, further comprising a catheter in communication with the apparatus volume, the elongate member extending through the catheter into the apparatus volume.

4. The apparatus of claim 3, wherein the elongate member is formed of a shape memory alloy, the elongate member being shaped to provide asymmetric placement of the spaced apart solid radiation sources, taking on a substantially straight shape while being inserted through the

catheter to the apparatus volume, and resuming an asymmetric shape when extended into the apparatus volume.

5. [The apparatus of claim 1,] A surgical apparatus for providing radiation treatment to target tissue comprising:

an expandable outer surface defining an apparatus volume;

a radiation source replaceably disposable within the expandable outer surface, the radiation source comprising a plurality of solid radiation sources arranged to provide predetermined asymmetric isodose curves within the target tissue, wherein at least one of the plurality of solid radiation sources has a different specific activity from at least one other solid radiation source.

6. [The apparatus of claim 1, wherein] A surgical apparatus for providing radiation treatment to target tissue comprising:

an expandable outer surface defining an apparatus volume;

a radiation source replaceably disposable within the expandable outer surface, the radiation source comprising a plurality of solid radiation sources arranged to provide predetermined asymmetric isodose curves within the target tissue, the plurality of radiation sources [are] being provided on at least two elongate members extending into the apparatus volume, at least one of the elongate members being shaped to provide asymmetric placement of a radiation source with respect to a longitudinal axis through the apparatus volume.

7. The apparatus of claim 6, wherein each of the at least two elongate members includes a plurality of solid radiation sources provided in a spaced apart relationship.

8. ~~The apparatus of claim 1, wherein the expandable outer surface is sufficiently rigid to~~ deform the target tissue into the shape of the expandable outer surface, causing the predetermined asymmetric isodose curves to penetrate into the target tissue to a prescribed depth.

9. An interstitial brachytherapy apparatus for treating target tissue surrounding a surgical extraction comprising:

an expandable outer surface having a base and defining [an] a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated;

a radiation source [replaceably disposable] disposed completely within and spaced apart from the expandable outer surface; and

an asymmetric radiation shield spaced apart from the radiation source, the asymmetric radiation shield providing predetermined asymmetric isodose curves [within the target tissue] with respect to the apparatus volume.

10. The apparatus of claim 9, wherein the asymmetric radiation shield comprises a radio-opaque material disposed on only a portion of the expandable outer surface.

11. The apparatus of claim 10, wherein the expandable outer surface comprises an inflatable balloon.

12. The apparatus of claim 11, wherein the radiation shield comprises a barium material disposed a portion of the inflatable balloon.

13. The apparatus of claim 9, further comprising at least one radiation shield extending from the base of the expandable outer surface toward an opposite end of the expandable surface, the shield being in between and spaced apart from the radiation source and the expandable outer surface, the shield forming a radio-opaque barrier between a portion of the radiation source and the target tissue.

14. The apparatus of claim 13, wherein the radiation shield comprises two shields provided on opposite sides of the radiation source.

15. Canceled.

16. Canceled.

17. Canceled.

18. Canceled.

19. Canceled.

1054025.1

Exhibit RR

10-K 1 d10k.htm FORM 10-K

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2007

Or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 Or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number: 001-33382

SENORX, INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0787406**
(State of Incorporation)	**(I.R.S. Employer Identification Number)**
11 Columbia, Suite A **Aliso Viejo, California**	**92656**
(Address of principal executive offices)	**(Zip Code))**

Registrant's telephone number, including area code: (949) 362-4800

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	**Name of each exchange on which registered:**
Common Stock, par value $0.001	**The NASDAQ Stock Market, LLC (NASDAQ Global Market)**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☐
(Do not check if a smaller reporting company)

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the registrant's common stock, held by non-affiliates of the registrant as of June 29, 2007 (which is the last business day of registrant's most recently completed second fiscal quarter) based upon the closing price of such stock on the NASDAQ Global Market on that date, was $111,260,549. For purposes of this disclosure, shares of common stock held by entities and individuals who own 5% or more of the outstanding common stock and shares of common stock held by each officer and director have been excluded in that such persons may be deemed to be "affiliates" as that term is defined under the Rules and Regulations of the Securities Exchange Act of 1934. This determination of affiliate status is not necessarily conclusive.

At February 29, 2008, the Registrant had 17,204,834 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10, 11, 12, 13 and 14 of Part III of this Form 10-K incorporate information by reference from the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this annual report.

Table of Contents

SENORX, INC.
FISCAL YEAR 2007 FORM 10-K ANNUAL REPORT

TABLE OF CONTENTS

PART I

PART II

PART III

PART IV

Table of Contents

ITEM 6. SELECTED FINANCIAL DATA

The following table presents selected historical financial data. We derived the selected statements of operations data for the years ended December 31, 2007, 2006 and 2005 and balance sheet data as of December 31, 2007 and 2006 from our audited financial statements and notes thereto that are included elsewhere in this annual report. We derived the selected statements of operations data for the years ended December 31, 2003 and the balance sheet data as of December 31, 2003 and 2004 from our audited financial statements that do not appear in this annual report.

You should read the following financial information together with the information under "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this annual report.

	Years Ended December 31,				
	2007	2006	2005	2004	2003
	(in thousands, except per share data)				
Statement of Operations Data:					
Net revenues	$35,036	$ 25,508	$19,253	$13,751	$10,277
Cost of goods sold (1)	15,124	13,506	10,105	6,415	4,829
Gross profit	19,912	12,002	9,148	7,336	5,448
Operating expenses:					
Selling and marketing (1)	19,023	15,041	10,148	7,507	7,974
Research and development (1)	6,354	5,323	4,903	4,790	4,928
General and administrative (1)	4,187	2,050	2,116	1,709	1,197
Total operating expenses	29,564	22,414	17,167	14,006	14,099
Loss from operations	(9,652)	(10,412)	(8,019)	(6,670)	(8,561)
Interest expense, net	7	850	594	148	95
Loss on debt extinguishment	1,265	197	—	—	—
Change in fair value of convertible promissory notes	(991)	3,960	—	—	—
Loss before provision for income taxes	(9,933)	(15,419)	(8,613)	(6,818)	(8,746)
Provision for income taxes	—	—	10	6	1
Net income (loss)	$ (9,933)	$(15,419)	$ (8,613)	$ (6,818)	$ (8,746)
Net loss per share—basic and diluted	$ (0.75)	$ (6.61)	$ (4.19)	$ (4.54)	$ (5.96)
Weighted-average shares outstanding basic and diluted (2)	13,309	2,332	2,060	1,504	1,468
(1)					
Includes all non-cash stock-based compensation expense as follows:					
Cost of goods sold	$ 110	$ 52	$ 34	$ 17	$ —
Selling and marketing	589	409	438	184	—
Research and development	509	395	286	184	—
General and administrative	883	220	563	416	8
Total	$ 2,091	$ 1,076	$ 1,321	$ 801	$ 8

(2) See Note 1 of the notes to our audited financial statements included elsewhere in this annual report for an explanation of the determination of the number of shares used in computing per share data.

Table of Contents

	As of December 31,				
	2007	2006	2005	2004	2003
			(in thousands)		
Balance Sheet Data:					
Cash and cash equivalents	$17,185	$ 7,413	$ 482	$ 3,703	$ 4,537
Working capital	32,894	7,386	2,308	4,578	3,666
Total assets	42,062	19,981	8,163	9,148	9,031
Long term obligations, less current portion	27	12,125	2,741	3,829	1,254
Convertible promissory notes (at fair value)	—	11,960	—	—	—
Convertible preferred stock	—	46,817	46,817	41,050	37,353
Total stockholders' equity (deficit)	34,363	(13,582)	658	1,922	(3,162)

Table of Contents

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the federal securities laws. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see the "Risk Factors" section in Item 1A of Part I of this Form 10-K. We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Form 10-K. We undertake no obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Form 10-K.

Overview

We develop, manufacture and sell minimally-invasive medical devices that are used in the diagnosis of breast cancer. We were incorporated in 1998. From our inception until 2002, our principal activity was the development and regulatory clearance of our initial products, primarily our biopsy tissue markers and our first breast biopsy system, the EnCor 360 (previously referred to by us and marketed as SenoCor 360). We launched our first biopsy tissue markers in 2002 and our EnCor 360 in 2003. The Encor 360 hardware subsequently served as a platform to facilitate the later launch of the EnCor probes, which are compatible with the major imaging modalities.

In 2004, we received 510(k) clearance from the FDA to market our EnCor breast biopsy system, our flagship product for use in breast biopsy procedures, conducting market preference testing commencing in the fourth quarter of 2004. Over the subsequent period ending in October 2005, we began selling the product on a limited basis while we focused on enhancing certain components of the product to optimize its performance, and we subsequently progressed with a full commercial launch of our EnCor system in November 2005.

We are currently developing minimally-invasive products for surgical excision of lesions and for breast cancer treatment. We received 510(k) clearance for our Contura Multi-Lumen Radiation Balloon Catheter, or Contura MLB, in May 2007 and launched in January 2008. We are also developing next generation tissue marker products, additional EnCor line extensions, line extensions of Contura MLB, and certain radio frequency based tissue cutting devices.

We have historically derived our revenues primarily from our tissue marker products. However, our EnCor system accounted for a majority of our revenue growth in 2007. Our ability to meet this expectation is based upon a number of assumptions, which may not ultimately occur, including growth of our sales force, growth in the market for minimally-invasive breast biopsy procedures and rapid adoption of the product by physicians who specialize in breast care. We expect our Contura MLB to rapidly become a significant contributor to our revenues and we intend to market this device as a compelling alternative to competing devices.

For the year ended December 31, 2007, we generated net revenues of $35.0 million and a net loss of $9.9 million. As of December 31, 2007, our accumulated deficit was $75.5 million. We have not been profitable since inception. We expect our operating expenses to increase as we expand our business to meet anticipated increased demand for our EnCor system, expand sales of our Contura MLB and devote resources to our sales and marketing and research and development activities.

Net Revenues

We derive our revenues primarily from the sales of our breast biopsy systems, breast biopsy capital, our tissue markers, and other products for breast care. Nearly all of our sales are generated in the United States and Canada, where we employ a direct sales force. Our breast biopsy systems, the EnCor and EnCor 360, consist of two primary components: reusable handpieces and disposable probes, and are used in conjunction with our SenoRx Breast Biopsy Console. The disposable probes form the basis of a recurring revenue stream and also contribute to the sales of tissue markers. Diagnostic adjunct revenue consists primarily of tissue marker sales, both used with our breast biopsy systems and with competitor's biopsy products. Our breast biopsy capital includes a reusable handpiece, a control module and

Exhibit SS

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

February 19, 2008
Date of Report (date of earliest event reported)

SENORX, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**001-33382**	**33-0787406**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

11 Columbia, Suite A, Aliso Viejo, California 92656
(Address of principal executive offices)

(949) 362-4800
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02. Results of Operations and Financial Condition.

On February 19, 2008, we are issuing a press release and holding a conference call regarding our financial results for the fourth quarter and full year ended December 31, 2007. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

This information shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of SenoRx, Inc. dated as of February 19, 2008.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SENORX, INC.

Date: February 19, 2008

By: /s/ Kevin J. Cousins
Kevin J. Cousins
Chief Financial Officer, Vice President, Finance

EX-99.1 2 dex991.htm PRESS RELEASE

Exhibit 99.1

PRESS RELEASE

SenoRx Reports Revenue Growth of 43.2 Percent in Q4 2007 Compared with Q4 2006

ALISO VIEJO, Calif., February 19 – SenoRx, Inc. (NASDAQ: SENO) today reported financial results for its fourth quarter and year ended December 31, 2007. Revenue for the quarter increased 43.2 percent to $10.3 million, compared with $7.2 million in the fourth quarter of 2006. Full-year revenue in 2007 grew 37.3 percent to $35.0 million compared with 2006.

For the fourth quarter of 2007, gross profit increased 84.0 percent to $5.8 million, or 55.9 percent of revenue, up from $3.1 million, or 43.5 percent of revenue, in the fourth quarter a year ago. SenoRx reported an operating loss for the fourth quarter of $2.9 million, compared with $3.2 million in the same period last year. The operating loss for the quarter included additional administrative expenses of approximately $342,000 incurred during the period associated with being a public company and stock-based compensation expense of $568,000, compared with $223,000 in the fourth quarter of 2006. In addition, sales and marketing expenses in the quarter included significant investment in supporting the pre-launch activities for Contura™ MLB, VisiLoc™ and SenoSonix™.

Net loss for the fourth quarter of 2007 was $4.0 million or 23 cents per share, compared with $3.9 million or $1.66 per share in the same period last year. Included in the results for the fourth quarter was a non-cash charge to non-operating expense of $1.3 million, or 7 cents per share for the quarter and 10 cents per share for the full year (variance due to the difference in average shares used to compute EPS for the year compared with the fourth quarter), related to the retirement of a subordinated debt facility with Escalate Capital, representing the unamortized debt issuance and debt discount costs that would have otherwise been charged to interest expense over the term of this loan facility. Retirement of this loan facility, which carried an interest rate of 11.5 percent per annum and did not carry a prepayment penalty, used approximately $10.3 million in cash, representing the principal balance and accrued unpaid interest. The company had previously announced that it intended to use a portion of its IPO cash proceeds to retire this loan facility prior to the end of 2007.

Lloyd Malchow, SenoRx President and Chief Executive Officer, said "Our fourth quarter results completed a strong finish to an exceptional year for SenoRx. Revenue for the quarter continued to grow strongly, led by a 43.1 percent

increase in biopsy disposable revenue over the same period a year ago, and an increase in biopsy capital equipment revenue of more than four times the fourth quarter of 2006."

For the fiscal year ended December 31, 2007, gross profit grew 65.9 percent to $19.9 million from $12.0 million a year ago. Gross margin in 2007 increased to 56.8 percent, up from 47.1 percent in 2006. Operating loss for the year declined to $9.7 million, compared with $10.4 million last year. Operating results included the impact of additional administrative expenses of approximately $1.3 million incurred during 2007 associated with being a public company and $2.1 million for stock-based compensation expense, compared with $1.1 million for stock-based compensation in 2006. Net loss for 2007 decreased 35.6 percent to $9.9 million, or 75 cents per share, compared with $15.4 million or $6.61 per share in 2006. Net loss for the year included the impact of the $1.3 million, or 10 cents per share, non-cash charge to non-operating expense related to the retirement of the Escalate loan facility during the fourth quarter.

"2007 marked the accomplishment of several key milestones," continued Malchow. "We maintained our track record of strong revenue growth, improved our gross margin substantially and positioned Contura MLB for its full commercial launch. We achieved strong continuing growth in the installed base of our EnCor systems, which grew to 536 units at the end of 2007, compared with 317 a year ago. Improved leverage of our manufacturing overhead across increased sales volume, ongoing cost reduction as we transition certain component manufacturing to low-cost suppliers, and leverage of our investments in tooling, all contributed to the improvement in gross margin. In addition, we introduced several new product innovations during 2007, including our first commercial sales of Contura MLB, which now establishes SenoRx in the therapeutic segment of the breast care market. We also launched our biopsy products in 10 additional countries through distribution partners."

"We are very excited about the opportunities for SenoRx in 2008 and beyond," concluded Malchow. "Initial orders for Contura MLB had expanded to include 34 clinical sites by the end of 2007, prior to the full commercial launch in January 2008. Our business model is focused on the growing market for interventional diagnostic and therapeutic products in breast care, while capitalizing on a consolidating customer base that facilitates efficiencies in sales and distribution and the opportunity to build critical mass with our portfolio of breast care products. We remain disciplined in our commitment to deliver strong ongoing growth through innovation, focus and execution."

SenoRx finished the year in a strong financial position with cash and short-term securities of $28.0 million. The company also continues to maintain a credit facility that allows it to borrow up to $4.0 million.

2008 Outlook

SenoRx reaffirms its initial estimate for 2008 revenue, which is expected to be in a range of $46 million to $50 million. In addition, SenoRx has estimated that deferred compensation and equity-based compensation expense will range between $2.8 million and $3.2 million for 2008. These ranges could be materially impacted based upon fluctuation in the market price of the company's common stock. In addition, the company estimates that patent litigation costs related to the complaint recently filed by Hologic could range between $1.4 million to $1.7 million during the year, in part due to the costs associated with defending a preliminary injunction that has been filed by Hologic to stop the sale of Contura MLB.

Conference Call

SenoRx will host a conference call at 8:00 a.m. Pacific Standard Time on Tuesday, February 19. The conference call can be accessed by calling 888-215-6899 (913-312-0977 for international callers) or via the company's website www.senorx.com.

About SenoRx

SenoRx (NASDAQ: SENO) develops, manufactures and sells minimally invasive medical devices used by breast care specialists for the diagnosis and treatment of breast cancer, including its flagship EnCor® system and Contura™ MLB. SenoRx's field sales organization serves over 1,000 breast diagnostic and treatment centers in the United States and Canada. With 18 products having received FDA 510(k) clearance across the continuum of breast care, SenoRx is developing additional minimally invasive products for diagnosis and treatment of breast cancer. For more information, visit the company's website at www.senorx.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Specifically, statements concerning expectations of future revenue growth and opportunities, the growing markets for SenoRx's products, the consolidation of the customer base, the ability to continue to innovate and execute, estimate of litigation costs, SenoRx's guidance for 2008, and the factors that would impact that guidance are forward-looking statements within the meaning of the Safe Harbor. Forward-looking statements are based on management's current, preliminary expectations and are subject to risks and uncertainties, which may cause SenoRx's actual results to differ materially from the statements contained herein. SenoRx's fourth quarter and year-end December 31, 2007 financial results, as discussed in this release, are preliminary and unaudited, and subject to adjustment. Further information on

potential risk factors that could affect SenoRx's business and its financial results are detailed in its most recent quarterly report on Form 10-Q as filed with the Securities and Exchange Commission. Undue reliance should not be placed on forward-looking statements, especially guidance on future financial performance, which speaks only as of the date they are made. SenoRx undertakes no obligation to update publicly any forward-looking statements to reflect new information, events or circumstances after the date they were made, or to reflect the occurrence of unanticipated events.

SENORX, INC.
BALANCE SHEETS

	December 31, 2007	December 31, 2006
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 17,185,259	$ 7,412,986
Short-term investments	10,764,490	—
Accounts receivable, net of allowance for doubtful accounts of $107,728 and $120,000, respectively	5,421,184	4,241,307
Inventory	6,650,955	4,988,695
Prepaid expenses and deposits	544,276	220,659
Total current assets	40,566,164	16,863,647
Property and equipment, net	1,071,435	1,100,599
Other assets, net of accumulated depreciation of $436,380, and $539,602, respectively	424,649	2,017,079
TOTAL	$ 42,062,248	$ 19,981,325
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$ 2,580,249	$ 4,122,477
Accrued expenses, including accrued employee compensation of $1,137,889 and $898,190, respectively	2,904,603	2,109,226
Deferred revenue—current	93,888	36,050
Current portion of long-term debt	2,093,346	3,209,621
Total current liabilities	7,672,086	9,477,374
Long-term debt—less current portion	26,820	10,596,147
Warrant liability	—	1,529,250
Total long-term liabilities	26,820	12,125,397
Convertible promissory notes (at fair value)	—	11,960,000
Commitments and contingencies		
Stockholders' Equity (Deficit):		
Series A convertible preferred stock—$1.00 par value; 3,000,000 shares authorized, issued and outstanding (2006) (aggregate liquidation value of $3,000,000)	—	3,000,000
Series B convertible preferred stock—$2.50 par value; 3,532,040 shares authorized; 3,523,040 issued and outstanding (2006) (aggregate liquidation value of $8,807,600)	—	8,807,600
Series C convertible preferred stock—$1.96 par value; 19,500,000 shares authorized; 17,861,899 (2006) issued and outstanding (aggregate liquidation value of $35,009,323)	—	35,009,323
Common stock, $0.001 par value—100,000,000 shares authorized; 17,202,395 (2007) and 2,371,002 (2006) issued and outstanding	17,202	2,371
Additional paid-in capital	109,815,612	5,262,394
Deferred compensation	—	(126,658)
Accumulated deficit	(75,469,472)	(65,536,476)
Total stockholders' equity (deficit)	34,363,342	(13,581,446)
TOTAL	$ 42,062,248	$ 19,981,325

SENORX, INC.
STATEMENTS OF OPERATIONS

	Three Months Ended December 31, (unaudited)		Years Ended December 31,	
	2007	2006	2007	2006
Net revenues	$10,308,389	$ 7,199,058	$35,035,836	$ 25,508,758
Cost of goods sold	4,540,904	4,064,616	15,123,897	13,506,272
Gross profit	5,767,485	3,134,442	19,911,939	12,002,486
Operating expenses:				
Selling and marketing	5,937,447	4,352,119	19,022,994	15,040,566
Research and development	1,658,431	1,456,424	6,353,430	5,322,557
General and administrative	1,094,430	545,518	4,187,133	2,050,450
Total operating expenses	8,690,308	6,354,061	29,563,557	22,413,573
Loss from operations	(2,922,823)	(3,219,619)	(9,651,618)	(10,411,087)
Interest expense	267,265	385,815	1,646,670	998,071
Loss on debt extinguishment	1,264,777	197,339	1,264,777	197,339
Change in fair value of convertible promissory notes and warrant valuation	—	140,000	(990,875)	3,960,000
Interest Income	(456,867)	(31,674)	(1,639,194)	(147,644)
Loss before provision for income taxes	(3,997,998)	(3,911,099)	(9,932,996)	(15,418,853)
Provision for income taxes	—	8,000	—	—
Net loss	$ (3,997,998)	$(3,903,099)	$ (9,932,996)	$(15,418,853)
Net loss per share-basic and diluted	$ (0.23)	$ (1.66)	$ (0.75)	$ (6.61)
Weighted average shares outstanding-basic and diluted	17,156,026	2,345,578	13,308,790	2,332,304

REVENUE BY PRODUCT CLASS

	Three Months Ended December 31, (unaudited)		Years Ended December 31,	
	2007	2006	2007	2006
Biopsy disposable products	$ 4,728,620	$ 3,304,951	$16,215,740	$ 10,972,421
Biopsy capital equipment products	1,171,614	225,321	3,301,908	1,245,279
Diagnostic adjunct products	4,078,672	3,668,786	14,976,567	13,291,058
Therapeutic disposables	329,483	—	541,621	—
Total	$10,308,389	$ 7,199,058	$35,035,836	$ 25,508,758

CONTACT:SenoRx, Inc.
Lila Churney, Director of Investor Relations
949.362.4800 ext.132


SENORX

Exhibit TT

SENORX INC

FORM 10-Q
(Quarterly Report)

Filed 11/13/07 for the Period Ending 09/30/07

Address	11 COLUMBIA SUITE A ALISO VIEJO, CA 92656
Telephone	949-362-4800
CIK	0001097136
Symbol	SENO
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment & Supplies
Sector	Technology

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2007

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____to _____

Commission File Number: 001-33382

SENORX, INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0787406**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

11 Columbia, Suite A
Aliso Viejo, California 92656
(Address of principal executive offices) (Zip Code)

(949) 362-4800
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐ *

Indicate by check mark whether the registrant is a Large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated Filer ☐ Accelerated filer ☐ Non-accelerated filer ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of October 31, 2007 17,149,485 shares of the registrant's common stock were outstanding.

Table of Contents

SENORX, INC.
INDEX

Table of Contents

ITEM I: FINANCIAL INFORMATON
SENORX, INC.
CONDENSED BALANCE SHEETS
(Unaudited)

	September 30, 2007	December 31, 2006
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 29,136,338	$ 7,412,986
Short-term investments	13,068,123	—
Accounts receivable, net of allowance for doubtful accounts of $113,169 and $120,000, respectively	5,338,554	4,241,307
Inventory	5,920,860	4,988,695
Prepaid expenses and deposits	691,797	220,659
Total current assets	54,155,672	16,863,647
Property and equipment, net	1,066,060	1,100,599
Other assets, net of accumulated depreciation of $442,956, and $539,602, respectively	539,899	2,017,079
TOTAL	$ 55,761,631	$ 19,981,325
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$ 1,622,402	$ 4,122,477
Accrued expenses, including accrued employee compensation of $786,914 and $507,829, respectively	2,801,971	2,109,226
Deferred revenue—current	66,850	36,050
Current portion of long-term debt	4,883,797	3,209,621
Total current liabilities	9,375,020	9,477,374
Long-term debt—less current portion	8,837,553	10,596,147
Warrant liability	—	1,529,250
Total long-term liabilities	8,837,553	12,125,397
Convertible promissory notes (at fair value)	—	11,960,000
Commitments and contingencies (Note 12)		
Stockholders' Equity (Deficit):		
Series A convertible preferred stock—$1.00 par value; 3,000,000 shares authorized, issued and outstanding (2006) (aggregate liquidation value of $3,000,000)	—	3,000,000
Series B convertible preferred stock—$2.50 par value; 3,532,040 shares authorized; 3,523,040 issued and outstanding (2006) (aggregate liquidation value of $8,807,600)	—	8,807,600
Series C convertible preferred stock—$1.96 par value; 19,500,000 shares authorized; 17,861,899 (2006) issued and outstanding (aggregate liquidation value of $35,009,323)	—	35,009,323
Common stock, $0.001 par value—100,000,000 shares authorized; 17,107,635 (2007) and 2,371,002 (2006) issued and outstanding	17,108	2,371
Additional paid-in capital	109,006,086	5,262,394
Deferred compensation	(2,662)	(126,658)
Accumulated deficit	(71,471,474)	(65,536,476)
Total stockholders' equity (deficit)	37,549,058	(13,581,446)
TOTAL	$ 55,761,631	$ 19,981,325

Table of Contents

SENORX, INC.
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Net revenues	$ 8,906,086	$ 6,147,677	$24,727,447	$ 18,309,700
Cost of goods sold	3,555,638	3,301,367	10,582,993	9,441,656
Gross profit	5,350,448	2,846,310	14,144,454	8,868,044
Operating expenses:				
Selling and marketing	4,354,056	3,588,887	13,085,547	10,688,447
Research and development	1,580,130	1,423,762	4,694,999	3,866,133
General and administrative	1,205,515	345,777	3,092,703	1,504,932
Total operating expenses	7,139,701	5,358,426	20,873,249	16,059,512
Loss from operations	(1,789,253)	(2,512,116)	(6,728,795)	(7,191,468)
Interest expense	452,670	231,017	1,379,405	612,256
Change in fair value of convertible promissory notes and warrant valuation	—	—	(990,875)	3,820,000
Interest Income	(551,288)	(55,262)	(1,182,327)	(115,970)
Loss before provision for income taxes	(1,690,635)	(2,687,871)	(5,934,998)	(11,507,754)
Provision for income taxes	—	3,000	—	8,000
Net loss	$ (1,690,635)	$(2,690,871)	$ (5,934,998)	$(11,515,754)
Net loss per share-basic and diluted	$ (0.10)	$ (1.15)	$ (0.50)	$ (4.98)
Weighted average shares outstanding-basic and diluted	17,076,002	2,331,054	11,973,240	2,313,663

Table of Contents

SENORX, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deferred Compensation	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances—December 31, 2006	3,000,000	$ 3,000,000	3,523,040	$ 8,807,600	17,861,899	$ 35,009,323	2,371,002	$ 2,371	$ 5,262,394	$ (126,658)	$ (65,536,476)	$ (13,581,446)
Proceeds from initial public offering, net of offering costs of $2,266,158							6,325,000	6,325	44,785,517			44,791,842
Proceeds from exercise of common stock options							52,064	52	52,586			52,638
Reclass of warrant liability to equity									698,374			698,374
Amortization of deferred compensation										123,996		123,996
Stock-based compensation									1,306,254			1,306,254
Employee stock purchase plan compensation									92,398			92,398
Conversion of promissory note							7,109,570	7,110	9,992,890			10,000,000
Conversion of preferred stock	(3,000,000)	(3,000,000)	(3,523,040)	(8,807,600)	(17,861,899)	(35,009,323)	1,249,999	1,250	46,815,673			—
Net loss											(5,934,998)	(5,934,998)
Balances—September 30, 2007	—	—	—	—	—	—	17,107,635	$ 17,108	$109,006,086	$ (2,662)	$ (71,471,474)	$ 37,549,058

Table of Contents

SENORX, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2007	2006
Cash Flows From Operating Activities:		
Net loss	$ (5,934,998)	$(11,515,754)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,056,766	643,819
Stock-based compensation	1,522,648	858,917
Loss on fixed asset abandonment	28,871	—
Provision for doubtful accounts	—	36,540
Amortization of debt discounts	306,189	157,771
Accretion of back-end interest on long-term debt	—	62,604
Change in fair value of convertible promissory notes and warrant debt discount	(990,875)	3,820,000
Changes in operating assets and liabilities:		
Accounts receivable	(1,097,247)	(558,292)
Inventory	(1,830,400)	(1,403,167)
Prepaid expenses and deposits	(471,138)	(82,059)
Other assets	469,384	(271,849)
Accounts payable	(2,518,879)	214,952
Accrued expenses	694,745	891,864
Deferred revenue	30,800	(61,284)
Net cash used in operating activities	(8,734,134)	(7,205,938)
Cash Flows From Investing Activities:		
Short-term investments	(13,068,123)	—
Acquisition of property and equipment	(389,422)	(469,584)
Net cash used in investing activities	(13,457,545)	(469,584)
Cash Flows From Financing Activities:		
Proceeds from issuance of common stock from stock option exercises	52,638	1,022,921
Proceeds from initial public offering	47,058,000	—
Payment of deferred offering costs	(941,027)	(414,124)
Proceeds from convertible promissory note	—	8,000,000
Proceeds from other borrowings	2,750,000	2,781,039
Payment of debt issuance costs	(49,496)	—
Repayment of other borrowings	(4,949,984)	(1,320,030)
Repayment of capital leases	(5,100)	—
Net cash provided by financing activities	43,915,031	9,149,176
Net increase in cash and cash equivalents	21,723,352	1,473,654
Cash and cash equivalents—beginning of period	7,412,986	482,259
Cash and cash equivalents—end of period	$ 29,136,338	$ 1,955,913
Supplemental Disclosure of Cash Flow Information:		
Cash paid for income taxes	$ —	$ —
Cash paid for interest	$ 807,450	$ 353,281
Inventory transferred to other assets	$ 665,741	$ —
Inventory transferred to fixed assets	$ 232,494	$ —
Property and equipment acquired included in accounts payable	$ 18,804	$ 51,989
Net fixed assets transferred to other assets	$ 26,512	$ —
Deferred offering costs offset against proceeds of initial public offering	$ 1,325,131	$ —
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ 1,028,007
Equipment acquired under capital leases	$ 14,477	$ —
Warrant liability transferred to equity	$ 698,374	$ —
Promissory note converted to common stock	$ 10,000,000	$ —
Preferred stock converted to common stock	$ 46,816,923	$ —

Table of Contents

SENORX, INC.
NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

BASIS OF PRESENTATION

The accompanying unaudited condensed financial statements have been prepared by SenoRx, Inc. (the "Company"), pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations, although the Company believes that the disclosures included in these notes and the accompanying condensed consolidated financial statements are adequate to make the information presented not misleading. The unaudited condensed financial statements reflect all adjustments, consisting only of normal recurring adjustments, that are, in the opinion of management, necessary to fairly state the financial position as of September 30, 2007 and the results of operations and cash flows for the related interim periods ended September 30, 2007 and 2006. The results of operations for the three and nine months ended September 30, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007 or for any other period.

The accounting policies followed by the Company and other information are contained in the notes to the Company's audited financial statements filed on February 21, 2007 as part of the Company's Registration Statement on Form S-1. This quarterly report should be read in conjunction with such report.

2. SIGNIFICANT ACCOUNTING POLICIES

The Company's significant accounting policies are disclosed in its Registration Statement on Form S-1 for the year ended December 31, 2006 which was filed with the Securities and Exchange Commission. The Company's significant accounting policies have not materially changed as of September 30, 2007.

3. RECENT ACCOUNTING PRONOUNCEMENTS

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements." SFAS No. 157 establishes a single authoritative definition of fair value, sets out a framework for measuring fair value, and requires additional disclosures about fair value measurements. SFAS No. 157 applies only to fair value measurements that are already required or permitted by other accounting standards. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the effect that the adoption of SFAS 157 will have on its financial position and results of operations

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities — Including an amendment of FASB Statement No. 115". SFAS 159 expands the use of fair value accounting to many financial instruments and certain other items. The fair value option is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the effect that the adoption of SFAS 159 will have on its financial position and results of operations.

In May 2007, the FASB issued FASB Staff Position FIN 48-1, "Definition of Settlement in FASB Interpretation No. 48". FIN 48-1 provides guidance on how to determine whether a tax position is effectively settled for the purpose of recognizing previously unrecognized tax benefits. FIN 48-1 is effective retroactively to January 1, 2007. The implementation of this standard did not have a material impact on the Company's financial position or results of operations.

In June 2007, the FASB ratified EITF 06-11 "Accounting for Income Tax Benefits of Dividends on Share-Based Payment Awards". EITF 06-11 provides that tax benefits associated with dividends on share-based payment awards be recorded as a component of additional paid-in capital. EITF 06-11 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007. The Company is currently evaluating the effect that the adoption of EITF 06-11 will have on its financial position and results of operations.

4. INITIAL PUBLIC OFFERING

The Company registered the initial public offering of its common stock, par value $.001 per share, in a Registration Statement on Form S-1 (Registration No. 333-134466), which was declared effective on March 28, 2007. The Company completed its initial public offering ("IPO") and sold 5,500,000 shares at $8.00 per share on April 3, 2007. Additionally, on April 20, 2007, the underwriters the IPO exercised their overallotment option to purchase an additional 825,000 shares at $8.00. Total expenses from the offering were approximately $5.8 million, which included underwriting discounts and commissions of $3.5 million, and approximately $2.2 million in other offering-related expense. Net offering proceeds, including the sale of shares pursuant to the subsequent underwriters overallotment and after deducting total expenses was $44.8 million. Upon the closing of the IPO, all of the outstanding shares of the Company's convertible preferred stock converted to 7,109,570 shares of the Company's common stock. In addition, the May 2006 Notes were converted into 1,249,999 shares of common stock.

SENORX, INC.
NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

5. SHORT-TERM INVESTMENTS

The Company's short-term investments consist of commercial paper. The Company accounts for its investments in marketable securities under FASB No. 115, "Accounting for Certain Investments in Debt and Equity Securities". Investments are recorded at amortized cost and are classified as held to maturity based on the Company's intent and ability to hold such investments until maturity.

6. INVENTORY

Inventories consist of the following:

	September 30, 2007	December 31, 2006
Raw materials	$3,273,082	$2,855,169
Work-in-process	494,058	178,284
Finished goods	2,153,720	1,955,242
	$5,920,860	$4,988,695

7. LONG-TERM DEBT

Working Capital Facility— On February 20, 2007, the Company amended the terms of its working capital facility extending the expiration date to February 2009. The amendment provided for increasing the aggregate limit on the working capital line from $3.5 million to $4.0 million and increased the advance rates on qualified accounts receivables from 75% to 80%. The working capital agreement, as amended, requires monthly interest payments at the bank's prime rate plus 1.25% (9.0% at September 30, 2007) subject to minimum interest rate of 9.0%. In addition, the existing quick ratio and net revenue covenants have been replaced with a minimum tangible net worth requirement. At September 30, 2007, the outstanding balance was $2,750,000, with $685,068 in borrowings available and the Company was in compliance with all covenants.

2006 Subordinated Note— On December 8, 2006, the Company entered into a subordinated loan and security agreement with Escalate Capital, LLC for advances of up to $10,000,000, which was fully advanced to the Company as of December 31, 2006 (the "December 2006 Subordinated Note"). This obligation bears interest at the rate of 11.5% per annum and is repayable in monthly interest only installments beginning November 30, 2006. However, at the option of the Company, 300 basis points of the accrued interest due through April 30, 2008 may be deferred until the maturity date of October 31, 2010. The Company has made this election and such amount will be added to the principal amount due and will accrue interest at 11.5%. The aggregate advances outstanding on the expiration of the drawdown period of June 30, 2007 shall be repaid in thirty (30) equal principal installments with the first installment due on May 30, 2008. The loan includes affirmative as well as negative covenants and is secured by substantially all of the Company's assets. At September 30, 2007, the Company was in compliance with these covenants.

The Company has the option to prepay the loan prior to maturity with no premium or penalty. In connection with the committed line, the Company paid a non-refundable facility fee of $100,000, and issued warrants to purchase up to 206,742 shares of the Company's Series C Preferred stock, vesting over one year, as defined, at an exercise price of $6.86 per share. Upon completion of the IPO in April 2007, the warrant converted into a warrant to purchase 206,742 shares of common stock at an exercise price of $6.86 per share. The warrants expire on the third anniversary of the closing of the initial public offering of the Company's common stock. The warrant allows for the exercise of the warrants after the one year anniversary of the issue date.

The warrant was previously carried as a liability on the Company's balance sheet at its fair value with increases or decreases in fair value at each reporting date recorded in the statement of operations. Upon completion of the IPO, the Company had registered shares sufficient to settle the warrant upon exercise. Accordingly, all requirements for equity classification of such warrant as described in EITF 00-19 were met effective April 3, 2007. In accordance with EITF 00-19, the warrant liability was reclassified to equity on April 3, 2007 and the gains recorded to account for the contract at fair value during the period the contract was classified as a liability were not reversed. The Company recorded income related to the change in fair value of $830,875 in the statement of operations for the nine months ended September 30, 2007. The fair value

SENORX, INC.
NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

of the warrant as of April 3, 2007 was estimated using the Black-Scholes option pricing method with the following assumptions: expected volatility rate of 43%; risk free interest rate of 4.5%, a term of three years and closing stock price on April 3, 2007 of $8.24. In addition, $1,529,250 has been capitalized as part of debt discount costs as of the date of issuance and is being recognized as additional interest expense over the life of the loan.

8. CONVERTIBLE PROMISSORY NOTES

May 2006 Notes — On May 4, 2006, the Company sold convertible promissory notes with an aggregate principal amount of $8,000,000 to one affiliated institutional investor and two unrelated institutional investors (the "May 2006 Notes"). The Company determined that the May 2006 Notes contained certain features that required bifurcation as embedded derivatives under SFAS No. 133, such as the IPO conversion feature. Therefore, in accordance with SFAS No. 155, the Company made an irrevocable election to measure the May 2006 Notes and the embedded derivatives, in their entirety, at fair value with subsequent changes in fair value recognized in the statement of operations.

At the date of the successful completion of the IPO on April 3, 2007, the fair value of the May 2006 Notes were $11,800,000, comprised of the $8,000,000 face value of the notes, $1,800,000 million in interest and $2,000,000 associated with the stock discount. Consequently, the Company adjusted the fair value of the May 2006 Notes to $11,800,000 and recorded the change in fair value of $160,000 in the statement of operations for the nine months ended September 30, 2007. In connection with the IPO, the May 2006 Notes were converted to 1,249,999 shares of common stock.

9. STOCKHOLDERS' EQUITY

In March 2007, the Company amended its certificate of incorporation to reflect a 1-for-3.5 reverse stock split of common stock. All share and per share amounts relating to common stock and stock options included in the accompanying condensed financial statements and footnotes have been restated to reflect the reverse stock split.

Authorized Shares of Common and Preferred Stock

Effective April 2, 2007, the Company amended and restated its certificate of incorporation to increase the authorized shares of common stock to 100,000,000 and created 10,000,000 shares of undesignated preferred stock.

10. STOCK OPTION PLANS

On February 16, 2007, the Company's board of directors approved increasing the number of shares of Common Stock authorized under the 1998 Stock Option Plan by 214,285 shares to a new total of 1,992,856 shares. In addition, the board of director's approved, under the Company's 1998 stock option plan, the issuance of options to employees to purchase an aggregate of 212,981 shares of common stock at an initial exercise price of $12.005 per share, which was the estimated fair market value of a share of common stock on the date of grant.

On May 7, 2007, the Company's board of directors approved, under the Company's 2006 equity incentive plan, the issuance of options to employees to purchase an aggregate of 82,605 shares of common stock at an exercise price of $8.00 per share, which was the fair market value of a share of common stock on the date of grant.

On June 14, 2007, the Company's board of directors approved, under the Company's 2006 equity incentive plan, the issuance of options to employees and a director to purchase an aggregate of 76,500 shares of common stock at an exercise price of $10.36 per share, which was the fair market value of a share of common stock on the date of grant.

On August 20, 2007, the Company's board of directors approved, under the Company's 2006 equity incentive plan, the issuance of options to employees to purchase an aggregate of 118,500 shares of common stock at an exercise price of $8.89 per share, which was the fair market value of a share of common stock on the date of grant.

On September 26, 2007, the Company's board of directors approved, under the Company's 2006 equity incentive plan, the issuance of options to employees to purchase an aggregate of 36,250 shares of common stock at an exercise price of $8.16 per share, which was the fair market value of a share of common stock on the date of grant

As of September 30, 2007, there was unrecognized compensation expense of $2.5 million related to stock option grants, which the Company expects to recognize over a weighted-average period of two years. The aggregate intrinsic value of options exercised during the nine months ended September 31, 2007 was $8.48.

SENORX, INC.
NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

Employee Stock Purchase Plan

Effective April 3, 2007, the closing date of the IPO, the Employee Stock Purchase Plan ("Purchase Plan") was established. The Company's Purchase Plan was adopted by the Company's board of directors effective as of May 2006 and approved by the Company's stockholders in June 2006. The Purchase Plan provides eligible employees of the Company with an incentive by providing a method whereby they may voluntarily purchase common stock of the Company upon terms described in the Purchase Plan. The Purchase Plan is designed to be operated on the basis of six consecutive month offering periods commencing April 1 and October 1 of each year during the term of the Purchase Plan, except for the first such offering period, which commenced on the first trading day on or after March 28, 2007 and ended on the first trading day on or after September 30, 2007. In June 2007, the Company's board of directors amended the offering periods to May 15 and November 15 of each year from April 1 and October 1 of each year commencing in 2008. The 2006 Purchase Plan terminates in 2016. The Purchase Plan provides that eligible employees may authorize payroll deductions of up to 10% of their salary to purchase shares of the Company's common stock at 85% of the fair market value of common stock on the first or last day of the applicable purchase period. As of September 30, 2007, Purchase Plan participant contributions of $236,226 were included in other current liabilities in the accompanying condensed balance sheet. A total of 550,000 shares of common stock are authorized for issuance under the Purchase Plan, and as of October 1, 2007, 34,708 shares have been issued under the Purchase Plan.

Director Compensation

Each outside director receives for his services on the board, $3,750 per meeting attended in person, or $1,500 per meeting attended telephonically. Each outside director who serves on the Company's audit committee or compensation committee also receives, for his or her service on such committee, $1,000 per meeting attended in person, or $500 per meeting attended telephonically. In addition, the chairpersons of the audit and compensation committees will each annually receive $8,500 and $4,250, respectively, which will be paid on a quarterly basis, in consideration for their services in these respective roles. Directors may be reimbursed for expenses incurred in connection with their attendance at board and committee meetings.

In addition, any new outside director, will be granted an initial option to purchase 20,000 shares of the Company's common stock. The initial option grants become exercisable as to 1/36 of the shares each month following the date of grant, subject to the director's continued service on each relevant vesting date. Beginning in 2007, outside directors who have been directors for at least six months also received a subsequent option to purchase 6,750 shares of the Company's common stock on the date of each annual stockholder's meeting for each year thereafter. Such option will also become exercisable as to 1/36 of the shares each month following the date of grant, subject to the director's continued service on each relevant vesting date. The Company's directors were issued options to purchase an aggregate of 120,000 shares of common stock at $8.00 per share as a result of the closing of the IPO, options to purchase 20,000 shares of common stock at $10.36 per share due to the subsequent appointment of a new director and options to purchase 40,500 shares of common stock at $9.55 per share due to the automatic grant to directors with over six months service on June 1, 2007.

11. INCOME TAXES

On January 1, 2007, the Company adopted Financial Accounting Standards Board Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" (FIN 48). FIN 48 prescribes a comprehensive model of how a company should recognize, measure, present, and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return. FIN 48 states that a tax benefit from an uncertain position may be recognized if it is "more likely than not" that the position is sustainable, based upon its technical merits. The tax benefit of a qualifying position is the largest amount of tax benefit that is greater than 50 percent likely of being realized upon ultimate settlement with a taxing authority having full knowledge of all relevant information.

Upon adoption of FIN 48, the Company would have decreased retained earnings $410,000, except that the decrease was fully offset by the release of a valuation allowance. In addition, future changes in the unrecognized tax benefit will have no impact on the effective tax rate due to the existence of the valuation allowance. The Company estimates that the unrecognized tax benefit will not change significantly within the next twelve months. The Company will continue to classify income tax penalties and interest as part of general and administrative expense in its Statements of Operations. Accrued interest on uncertain tax positions is not significant as of September 30, 2007. There are no penalties accrued as of September 30, 2007. The following table summarizes the open tax years for each major jurisdiction:

Jurisdiction	Open Tax Years
Federal	1998 - 2006
California	1998 - 2006

Table of Contents

SENORX, INC.
NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

12. NET LOSS PER SHARE

Basic loss per share is based on the weighted-average number of shares of common stock outstanding during the period. Diluted loss per share also includes the effect of stock options, warrants and other common stock equivalents outstanding during the period. In periods of a net loss position, basic and diluted weighted average shares are the same.

The following table sets forth the computation of denominator used in the computation of net loss per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Weighted-average common stock outstanding	17,096,433	2,353,242	11,993,671	2,370,633
Less: Unvested common shares subject to repurchase	(20,431)	(39,579)	(20,431)	(39,579)
Total weighted-average number of shares used in computing net loss per share-basic and diluted	17,076,002	2,313,663	11,973,240	2,331,054

13. LITIGATION

The Company may be subject to legal proceedings, claims and litigation arising in the ordinary course of business. While the amounts claimed may be substantial, the ultimate liability cannot presently be determined because of considerable uncertainties that exist. Therefore, it is possible the outcome of such legal proceedings, claims and litigation could have a material effect on quarterly or annual operating results or cash flows when resolved in a future period. However, based on facts currently available, management is not aware of any matters that could have a material adverse effect on the Company's financial position, results of operations or cash flows.

14. SEGMENT INFORMATION

Net revenues by geographic area are presented based upon the country of destination. No foreign country represented 10% or more of net revenues for any period presented. Net revenues by geographic area were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
United States and Canada	$8,446,449	$5,876,190	$23,759,576	$17,692,549
Rest of world	459,637	271,487	967,871	617,151
Total	$8,906,086	$6,147,677	$24,727,447	$18,309,700

No customer accounted for 10% or more of net revenues for any period presented.

At September 30, 2007, the Company has four product classes. In June 2007, the Company revised its product classes to reflect the manner in which it now assesses its performance and makes decisions. Biopsy disposable products include the Company's EnCor and SenoCor products. Biopsy capital equipment products include the consoles and other pieces (non-disposable) of the EnCor and SenoCor products. Diagnostic adjunct products include the Marker product, the Gamma Finder product and the Anchor Guide product. Therapeutic disposables include the Company's recently commercialized Contura Multi-Lumen Balloon (MLB) Catheter, which received FDA 510(k) clearance in May 2007.

Table of Contents

SENORX, INC.
NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

Net revenues by product class are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Biopsy disposable products	$3,945,941	$2,723,793	$11,487,122	$ 7,667,470
Biopsy capital equipment products	1,029,065	294,494	2,130,294	1,019,958
Diagnostic adjunct products	3,744,039	3,129,390	10,897,893	9,622,272
Therapeutic disposables	187,041	—	212,138	—
Total	$8,906,086	$6,147,677	$24,727,447	$18,309,700

Substantially all of the Company's assets are in the United States.

Table of Contents

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the federal securities laws. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see the "Risk Factors" section in Item 1A of Part II of this Form 10-Q. We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Form 10-Q. We undertake no obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Form 10-Q.

Overview

We develop, manufacture and sell minimally invasive medical devices for the diagnosis of breast cancer. We were incorporated in 1998. From our inception until 2002, our principal activity was the development and regulatory clearance of our initial products, primarily our biopsy tissue markers and our first breast biopsy system, the SenoCor 360. We launched our first tissue markers in 2002 and our SenoCor 360 in 2003.

In 2004, we received 510(k) clearance from the FDA to market our EnCor breast biopsy system, our flagship diagnostic product, conducting market preference testing commencing in the fourth quarter of 2004. Over the subsequent period ending in October 2005, we began selling the product on a limited basis while we focused on enhancing certain elements of the product to optimize its performance, and we subsequently progressed with a full commercial launch of our EnCor system in November 2005.

We are currently developing minimally invasive products for surgical excision of lesions and for breast cancer treatment. We received 510(k) clearance for our Contura Multi-Lumen Balloon (MLB) Catheter in May of 2007. We are also developing breast surgery and breast reconstruction devices, our Single Step, and Shape Select, for which we respectively expect to enter limited launch phases in early 2009.

We have historically derived our revenues primarily from our tissue marker products. However, our EnCor system accounted for a majority of our revenue growth in 2006, and we expect this to continue for the foreseeable future. Our ability to meet this expectation is based upon a number of assumptions, which may not ultimately occur, including growth of our sales force, growth in the market for minimally invasive breast biopsy procedures and rapid adoption of the product by physicians who specialize in breast care. We expect our Contura MLB Catheter to rapidly become a significant contributor to our revenues. We continue to develop and market this device as a compelling alternative to competing devices as we prepare for full commercialization.

For the nine months ended September 30, 2007, we generated net revenues of $24.7 million and a net loss of $5.9 million. As of September 30, 2007, our accumulated deficit was $71.5 million. We have not been profitable since inception. We expect our operating expenses to increase as we expand our business to meet anticipated increased demand for our EnCor system, seek regulatory clearance and prepare for the full commercialization of our Contura MLB Catheter and devote resources to our sales and marketing and research and development activities.

In the second half of 2006, as a part of our settlement of litigation with Suros Surgical Systems (now a wholly-owned subsidiary of Hologic), we implemented a design modification to the EnCor system cutter. This effort resulted in a short-term decrease in yields, the obsolescing of certain inventory and a delay in implementing certain cost improvements related to production and manufacturing, which had an adverse effect on our costs of goods sold for the third and fourth quarters of 2006. Additionally, our third quarter 2006 revenues were adversely impacted by our efforts earlier in the year to integrate a large number of newly-hired sales representatives.

Net Revenues

We derive our revenues primarily from the sales of our breast biopsy systems, breast biopsy capital, our tissue markers, and other products for breast care. Nearly all of our sales are generated in the United States and Canada, where we employ a direct sales force. Our breast biopsy systems, the EnCor and SenoCor 360, consist of two primary components: reusable handpieces and disposable probes, and are used in conjunction with our SenoRx Breast Biopsy Console. The disposable probes form the basis of a recurring revenue stream and also contribute to the sales of tissue markers. Diagnostic adjunct revenue consists primarily of tissue marker sales, both used with our breast biopsy systems and with competitor's biopsy products. Our breast biopsy capital includes a reusable handpiece, a control module and vacuum source used in conjunction with our disposable biopsy probe. We expect that the sales of biopsy disposable, biopsy capital and marker products will continue to grow in the fourth quarter of 2007. We further expect that the sales of our adjunct and excision products will also grow, though at a slower rate.

Cost of Goods Sold

Our cost of goods sold consists of the cost to manufacture and assemble our products, primarily including materials, components and labor. We assemble and package all of our finished products with the exception of our Gamma Finder product. We expect that our cost of goods sold will decrease, and, correspondingly, gross profits will increase, as a percentage of net revenues with increased sales volume, product enhancements and outsourced manufacturing efficiencies. At the end of 2005, we entered into an agreement with a contract manufacturer in Thailand and began to transfer a portion of our manufacturing for certain components of our products to this site, and we anticipate that we will transfer additional manufacturing to this site in order to increase gross margins. We anticipate that our gross margin will continue to increase in the fourth quarter of 2007 due to design and production process improvements, the manufacturing efficiencies that we expect to see with increased production, and the continued successful transfer of manufacturing of certain products and product components to our Thailand contract manufacturer.

Operating Expenses

Our operating expenses consist of research and development, selling and marketing, and general and administrative expenses. Stock-based compensation, a non-cash item, is primarily included in these expenses.

Our research and development expenses consist of salaries and related expenses of our research and development personnel and consultants and costs of product development, which include patent filing and maintenance costs, production engineering, clinical and regulatory support and post-clearance clinical product enhancements. We expense all our research and development costs as they are incurred. We expect research and development expenses to increase in absolute terms as we continue to develop, enhance, obtain clinical results and commercialize existing and new products; however, for 2007, we believe that research and development expenses will remain approximately equivalent to the expenses incurred in 2006.

Our selling and marketing expenses consist of salaries and related expenses of our direct sales team and sales management, travel, clinical education and training expenses, marketing and promotional expenses, and costs associated with tradeshows. We expect selling and marketing expenses to increase in absolute terms as we expand our sales organization and promotional activities.

Our general and administrative expenses consist of the cost of corporate operations, litigation and professional services. We expect general and administrative expenses to increase in absolute dollars as we increase our infrastructure to comply with the regulatory requirements associated with publicly-traded companies.

Over the next several years, we will incur non-cash expenses for employee stock-based compensation, decreasing quarterly, for stock options granted prior to January 1, 2006 and determined to have been issued at less than estimated fair value. We expect to incur additional stock-based compensation expense, primarily for options granted subsequent to January 1, 2006, which will be accounted for under SFAS No. 123R. We anticipate that non-cash expenses for options accounted for under SFAS No. 123R will remain at their current levels or increase based upon the number of options granted and the performance of the Company's common stock .

Interest

Interest represents income generated from our cash and cash equivalents and short-term investments which are invested generally in liquid money-market funds and commercial paper, offset by expense incurred on our debt obligations. These debt obligations include a working capital facility, an equipment facility and long-term notes payable. Interest expense also includes the fair value for any equity interests, such as warrants, granted in conjunction with the debt obligations. The fair value of the equity interests are amortized to interest expense over the term of the related debt obligations. We expect interest income to increase due to the receipt of proceeds from this offering.

Income Tax Expense

Due to uncertainty surrounding the realization of deferred tax assets through future taxable income, we have provided a full valuation allowance and no benefit has been recognized for our net operating loss and other deferred tax assets. Income tax expense relates to certain state taxes.

Table of Contents

Results of Operations

The following table sets forth our results of operations expressed as percentages of revenues for the three months ended September 30, 2007 and 2006:

	For the Three Months Ended September 30,	
	2007	2006
Net revenues	100.0%	100.0%
Cost of goods sold	39.9	53.7
Gross profit	60.1	46.3
Operating expenses:		
Selling and marketing	48.9	58.4
Research and development	17.7	23.2
General and administrative	13.5	5.6
Total operating expenses	80.2	87.2
Loss from operations	(20.1)	(40.9)
Interest expense	5.1	3.8
Interest income	(6.2)	(0.9)
Provision for income taxes	—	—
Net loss	(19.0)%	(43.8)%

Three months ended September 30, 2007 and 2006

Net Revenues . Net revenues increased $2.8 million, or 44.9%, to $8.9 million for the three months ended September 30, 2007 from $6.1 million for the three months ended September 30, 2006. The increase primarily consisted of an increase of $1.2 million in biopsy disposable revenues, or 44.9% from the three months ended September 30, 2006, due to a larger installed base of EnCor systems. Biopsy capital revenues increased $735,000, or 249.4% due to a greater number of customers purchasing our breast biopsy systems as compared to those customers acquiring the capital through a "product supply agreement" in 2006. Diagnostic adjunct revenues increased $615,000, or 19.6% primarily due to an increase in marker sales resulting from increased EnCor disposable biopsy sales and sales of markers used with competitive biopsy disposables. Therapeutic disposable revenues increased $187,000 as we began selling our Contura MLB Catheter product in June 2007 following FDA 510(k) clearance in May 2007.

Cost of Goods Sold and Gross Profit . Cost of good sold increased $254,000, or 7.7%, to $3.6 million for the three months ended September 30, 2007 from $3.3 million for the three months ended September 30, 2006. The increase in total cost of goods sold primarily consisted of an increase in direct labor, manufacturing overhead and material costs associated with our increase in product sales. Gross profit increased $2.5 million, or 88.0%, for the three months ended September 30, 2007 to $5.4 million from $2.8 million for the three months ended June 30, 2006. As a percentage of net revenues gross profit increased by 13.8% to 60.1% for the three months ended September 2007 from 46.3% in June 2006. The increase in gross profit as a percentage of net revenues was primarily attributable to improved efficiencies in the production of our disposable biopsy probe and allocating manufacturing overhead over greater product revenues and inventory unit production.

Selling and Marketing Expenses . Selling and marketing expenses increased $765,000, or 21.3%, to $4.4 million for the three months ended September 30, 2007 from $3.6 million for the three months ended September 30, 2006. The increase primarily consisted of $619,000 in salaries and related employee costs due to the expansion of our sales organization, an increase of $97,000 in sales promotion related activities and $49,000 in equity based compensation charges including deferred compensation and the discount associated with shares purchased by employees under our Employee Stock Purchase Plan

Research and Development Expenses . Research and development expenses increased $156,000, or 11.0%, to $1.6 million for the three months ended September 30, 2007 from $1.4 million for the three months ended September 30, 2006. The increase in these expenses primarily consisted of $38,000 in salaries and the related employee costs, $49,000 associated with project costs for the development of the Contura MLB Catheter, $17,000 in patent, legal and professional fees related to the Contura MLB Catheter development. Additionally, equity based compensation charges including deferred compensation and the discount associated with shares purchased by employees under our Employee Stock Purchase Plan increased by $52,000.

General and Administrative Expenses . General and administrative expenses increased $857,000, or 245.6%, to $1.2 million for the three months ended September 30, 2007 from $346,000 for the three months ended September 30, 2006. The increase primarily consisted of $133,000 related to increased headcount and increased compensation, $247,000 in equity based compensation charges including deferred compensation and the discount associated with shares purchased by employees under our Employee Stock Purchase Plan, $338,000 for public company related costs including legal and reporting expenses, and $139,000 for departmental related expenses.

Interest Expense . Interest expense increased $222,000 to $453,000 for the three months ended September 30, 2007 from $231,000 for the three months ended September 30, 2006. The increase was due to the interest expense incurred relating to the December 2006 Subordinated Note payable.

Interest Income . Interest income increased $496,000 to $551,000 for the three months ended September 30, 2007 from $55,000 for the three months ended September 30, 2007 primarily as a result of increased interest income from the higher cash and short-term investment balances resulting from our IPO, which closed in April 2007.

Results of Operations

The following table sets forth our results of operations expressed as percentages of revenues for the nine months ended September 30, 2007 and 2006:

	For the Nine Months Ended September 30,	
	2007	2006
Net revenues	100.0%	100.0%
Cost of goods sold	42.8	51.6
Gross profit	57.2	48.4
Operating expenses:		
Selling and marketing	55.9	58.4
Research and development	19.0	21.1
General and administrative	12.5	8.2
Total operating expenses	84.4	87.7
Loss from operations	(27.2)	(39.3)
Interest expense	5.6	3.3
Change in fair value of convertible promissory notes and warrant valuation	(4.0)	20.9
Interest income	(4.8)	(0.6)
Provision for income taxes	—	—
Net loss	(24.0)%	(62.9)%

Nine months ended September 30, 2007 and 2006

Net Revenues . Net revenues increased $6.4 million, or 35.1%, to $24.7 million for the nine months ended September 30, 2007 from $18.3 million for the nine months ended September 30, 2006. The increase primarily consisted of an increase of $3.8 million in biopsy disposable revenues, or 49.8% from the nine months ended September 30, 2006 due to a larger installed base of EnCor systems. Biopsy capital revenues increased $1.1 million, or 108.9% due to a greater number of customers purchasing our breast biopsy systems as compared to those customers acquiring the capital through a “product supply agreement” in 2006. Diagnostic adjunct revenues increased $1.3 million, or 13.3% primarily due to an increase in marker sales resulting from increased EnCor disposable biopsy sales and sales of markers used with competitive biopsy disposables and increased gamma finder sales. Diagnostic therapeutic revenues increased $212,000 as we began selling our Contura MLB Catheter product in June 2007 following the May 2007 FDA 510(k) clearance.

Cost of Goods Sold and Gross Profit . Cost of good sold increased $1.2 million, or 12.1%, to $10.6 million for the nine months ended September 30, 2007 from $9.4 million for the nine months ended September 30, 2006. The increase in total cost of goods sold primarily consisted of an increase in direct labor, manufacturing overhead and material costs associated with our increase in product sales. Gross profit increased $5.3 million or 59.5% for the nine months ended September 30, 2007 to $14.1 from $8.9 million for the nine months ended September 30, 2006. Gross profit as a percentage of net revenues increased by 8.8% to 57.2% for the nine months ended September 30, 2007 from 48.4% for the nine months ended September 30, 2006. The increase in gross profit as a percentage of net revenues was primarily attributable to improved efficiencies in the production of our disposable biopsy probe and allocating manufacturing overhead over greater product revenues and inventory unit production.

Selling and Marketing Expenses . Selling and marketing expenses increased $2.4 million, or 22.4%, to $13.1 million for the nine months ended September 30, 2007 from $10.7 million for the nine months ended September 30, 2006. The increase primarily consisted of $2.2 million in salaries and related employee costs due to the expansion of our sales organization, $102,000 in equity based compensation charges including deferred compensation and the discount associated with shares purchased by employees under our Employee Stock Purchase Plan, a $123,000 increase in selling and promotional related expenses which were partially offset by a $44,000 reduction in departmental expenses.

Research and Development Expenses . Research and development expenses increased $829,000, or 21.4%, to $4.7 million for the nine months ended September 30, 2007 from $3.9 million for the nine months ended September 30, 2006. The increase in these expenses primarily consisted of $197,000 in salaries and the related employee costs, $276,000 associated with project costs for the development of the Contura MLB Catheter, an increase of $315,000 in patent, legal and professional fess related to the Contura MLB Catheter development and a $41,000 increase in equity based compensation charges including deferred compensation and the discount associated with shares purchased by employees under our Employee Stock Purchase Plan.

General and Administrative Expenses . General and administrative expenses increased $1.6 million, or 104.4 %, to $3.1 million for the nine months ended September 30, 2007 from $1.5 million for the nine months ended September 30, 2006. The increase primarily consisted of $556,000 related to increased headcount and increased compensation, $700,000 for public company related costs, including legal and reporting expenses, $452,000 in equity based compensation charges including deferred compensation and the discount associated with shares purchased by employees under our Employee Stock Purchase Plan and $99,000 for increased departmental costs. These increases were partially offset by a $227,000 decrease in legal fees associated with the resolution of the Suros litigation in May 2006.

Interest Expense . Interest expense increased $767,000 to $1.4 million for the nine months ended September 30, 2007 from $612,000 for the nine months ended September 30, 2006. The increase was due to the interest expense incurred relating to the December 2006 Subordinated Note payable.

Change in Fair Value of Convertible Promissory Notes and Warrant Valuation. For the nine months ended September 30, 2007, we recorded an aggregate of $160,000 for the changes in fair value of our May 2006 Notes in accordance with FAS No. 155 and $831,000 for the reduction in the fair value of the warrant liability. For the nine months ended September 30, 2006, we recorded a $3.8 million expense for the changes in fair value of our May 2006 Notes.

Interest Income . Interest income increased $1.1 million to $1.2 million for the nine months ended September 30, 2007 from $116,000 for the nine months ended September 30, 2006 primarily as a result of increased interest income from higher cash and short-term investment balances resulting from our IPO, which closed in April 2007.

Liquidity and Capital Resources

General

We have incurred losses since our inception in January 1998 and, as of September 30, 2007, we had an accumulated deficit of $71.5 million. From inception through September 30, 2007, we generated cumulative gross profit from the sale of our product offerings of $50.9 million. To date, our operations have been funded primarily with proceeds from the issuance of our preferred stock and borrowings, including our issuance of the May 2006 Notes and the December 2006 Subordinated Note, as well as our IPO in April 2007. Cumulative net proceeds from the issuance of preferred stock totaled $46.8 million. Proceeds from the issuance of the May 2006 Notes totaled $8.0 million. Proceeds from the issuance of the December 2006 Subordinated Note were $10.0 million, of which $1.2 million was used to repay the 2004 subordinated note obligation. Net proceeds from our IPO, including the sale of shares pursuant to the subsequent underwriters overallotment and after deducting total expenses, was $44.8 million. All of our preferred stock converted into common stock upon the closing of the IPO.

We believe that our cash and cash equivalents and our anticipated ability to draw down on our working capital and equipment facilities, will be sufficient to meet our projected operating requirements for at least the next 12 months. We anticipate that we will continue to use cash in our operating activities and investing activities for the foreseeable future as we grow our business.

Net Cash Used in Operating Activities

Net cash used in operating activities was $8.7 million, for the nine months ended September 30, 2007, which was a function of a decrease in accounts payable and accrued expenses of $1.8 million, an increase in inventory of $1.8 million, an increase in accounts receivable of $1.1 million and an increase in prepaid expenses of $471,000. These uses of cash were partially offset by a decrease in other assets of $469,000 and an increase in deferred revenue of $31,000. The $1.8 million decrease in accounts payable and accrued expenses resulted from the use of proceeds from the April 2007 IPO which allowed us to reduce outstanding vendor balances. The aggregate increased investment in inventory of $1.8 million resulted primarily from two major factors, including (i) our decision to build shelf stock of our higher volume products in order to better service our customers, and (ii) the need to purchase longer-term quantities of certain parts due to long lead times. We expect inventory will continue to increase during the remainder of 2007. The increase in accounts receivable was primarily due to an increase in net sales. While we expect that the amount of accounts receivable will fluctuate based on the timing of sales and collections, we expect our ratio of overall investment in accounts receivable as compared to revenues will remain constant as compared to 2006.

Net Cash Used in Investing Activities

Net cash used in investing activities amounted to $13.5 million during the nine months ended September 30, 2007, was primarily attributable to the purchase of short-term investments and the addition of demonstration units and new manufacturing molds.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $44.0 million during the nine months ended September 30, 2007 was primarily attributable to proceeds of $47.1 million from the April 2007 IPO and underwriters overallotment, the $2.8 million advance on our working capital facility and $53,000 related to the proceeds from the issuance of common stock from option exercises. These proceeds were partially offset by an aggregate of $5.0 million in repayments under our various debt facilities and $941,000 in cash paid for deferred offering costs including legal, accounting and printing fees, which were reclassified to additional paid-in capital at the completion of the IPO in April 2007.

Off-Balance Sheet Arrangements

Since inception, we have not engaged in material off-balance sheet activities, including the use of structured finance, special purpose entities or variable interest entities.

Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements." SFAS No. 157 establishes a single authoritative definition of fair value, sets out a framework for measuring fair value, and requires additional disclosures about fair value measurements. SFAS No. 157 applies only to fair value measurements that are already required or permitted by other accounting standards. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. We are currently evaluating the effect that the adoption of SFAS 157 will have on our financial position and results of operations.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities — Including an amendment of FASB Statement No. 115". SFAS 159 expands the use of fair value accounting to many financial instruments and certain other items. The fair value option is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. SFAS 159 is effective for fiscal years beginning after November 15, 2007. We are currently evaluating the effect that the adoption of SFAS 159 will have on our financial position and results of operations.

In May 2007, the FASB issued FASB Staff Position FIN 48-1, "Definition of Settlement in FASB Interpretation No. 48". FIN 48-1 provides guidance on how to determine whether a tax position is effectively settled for the purpose of recognizing previously unrecognized tax benefits. FIN 48-1 is effective retroactively to January 1, 2007. The implementation of this standard did not have a material impact on our financial position or results of operations.

In June 2007, the FASB ratified EITF 06-11 "Accounting for Income Tax Benefits of Dividends on Share-Based Payment Awards". EITF 06-11 provides that tax benefits associated with dividends on share-based payment awards be recorded as a component of additional paid-in capital. EITF 06-11 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007. We are currently evaluating the effect that the adoption of EITF 06-11 will have on our financial position and results of operations.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and investments in a variety of marketable securities, including commercial paper, money market funds and corporate debt securities and U.S. government securities. Our cash and cash equivalents as of September 30, 2007, included liquid money market accounts. Due to the short-term nature of our investments, we believe we have no material exposure to interest rate risk. Additionally, since the majority of our debt carries interest at fixed rates, we also believe changes in interest rates will not cause significant changes in our interest expense. Our revenues are denominated in U.S. dollars. Accordingly, we have not had exposure to foreign currency rate fluctuations. We expect to continue to realize our revenues in U.S. dollars.

ITEM 4T. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures . Our management evaluated, with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to management as appropriate to allow for timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting . There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not a party to any material pending or threatened litigation.

ITEM 1A. RISK FACTORS

RISKS RELATED TO OUR BUSINESS

We have a limited history of operations and a history of net losses, and we may not be able to achieve profitability even if we are able to generate significant revenues.

We have a limited history of operations upon which you can evaluate our business. We began selling our first products in 2002 and fully launched our flagship product, the EnCor system, in November 2005. We incurred net losses of $8.6 million in 2005, $15.4 million in 2006, and $5.9 million in the nine months ended September 30, 2007, and, as of that date, had an accumulated deficit of approximately $71.5 million. In addition, we expect our operating expenses to increase as we expand our business to meet anticipated increased demand for our EnCor system, and prepare for the full commercialization of the Contura MLB Catheter and devote resources to our sales and marketing and research and development activities. In order for us to become profitable, we believe that our EnCor system must be widely adopted. We cannot assure you that we will be able to achieve or sustain profitability even if we are able to generate significant revenues. Our failure to achieve and sustain profitability would negatively impact the market price of our common stock and require us to obtain additional funding.

Our success depends upon market adoption of our EnCor system, without which our results of operations will suffer.

We have historically derived our revenue primarily from our tissue marker products. However, our EnCor system, launched in November 2005, accounts for a majority of our revenue growth, and we expect this to continue for the foreseeable future. Our ability to meet this expectation is based upon a number of assumptions, including:

- the adequacy of third-party reimbursement for the minimally invasive procedures in which EnCor is used;
- the market for minimally invasive breast biopsy procedures will continue to grow;
- we will be able to demonstrate compelling clinical data supporting EnCor's safety and effectiveness;
- key features of EnCor will represent compelling technological advancements to potential users;

- EnCor will be endorsed by key opinion leaders; and
- physicians who specialize in breast care will rapidly adopt EnCor.

Even if we are able to present potential customers with compelling clinical data, technological advancements or influential user experiences, they may be reluctant to switch from a competing device to which they have grown accustomed. We may not be successful in our near-term strategy of marketing EnCor to our existing customer base of tissue marker users, and users of our earlier vacuum-assisted breast biopsy system, our SenoCor 360. Our commercial success also depends on the continued general market shift to less invasive biopsy procedures. Failure of EnCor to be widely adopted would significantly harm our future financial performance.

Our future success will depend in part upon our ability to successfully commercialize our Contura MLB Catheter.

We expect our Contura MLB Catheter, which we received FDA 510(k) clearance in May 2007, to rapidly become a significant contributor to our revenues. The Contura MLB Catheter development has been completed but there remains significant challenges that must be overcome before it can be fully commercialized, including:

- we have limited experience selling to radiological oncologists, the primary market for this product;
- protecting it with intellectual property rights;
- obtaining adequate third-party reimbursement;
- producing compelling clinical data on safety and effectiveness;
- partnering, as necessary, with suppliers; and
- manufacturing it consistently within our specifications and in accordance with the FDA's Quality System Regulations.

If we are able to overcome these challenges, we may nevertheless be unable to convince potential customers that the Contura MLB Catheter represents a compelling alternative to competing products. Our commercial success will also depend on a general market shift from whole to partial breast radiation. Our long-term commercialization experience with the Contura MLB Catheter could be significantly below expectations or not achieved at all, which would have a material adverse effect on our future financial performance.

We have limited clinical data regarding the safety and efficacy of our products. If future data or clinical experience is negative, we may lose significant market share.

Our success depends on the acceptance of our products by the medical community as safe and effective. Physicians that may be interested in using our products may hesitate to do so without long-term data on safety and efficacy. The limited clinical studies on some of our products that have been published or presented as abstracts at major medical meetings typically have been based on the work of a small number of physicians examining small patient populations over relatively short periods. Accordingly, the results of these clinical studies do not necessarily predict long-term clinical results, or even short-term clinical results from the broader physician community. If future safety or efficacy data or clinical experience is negative, we may lose significant market share.

We compete against companies that have more established products and greater resources, which may prevent us from achieving significant market penetration or improved operating results.

Many of our products compete, and our future products may compete, against products that are more established and accepted within our target markets. With fewer resources and operating history than many of our competitors and potential future competitors, and a less-established reputation, it may be difficult for our products to gain significant market penetration. We may be unable to convince physicians to switch their practice away from competing devices. Competing effectively will require us to distinguish our company and our products from our competitors and their products, and turns on factors such as:

- ease of use and performance;
- price;
- quality and scale of our sales and marketing efforts;
- our ability to offer a broad portfolio of products across the continuum of breast care;
- establishing a strong reputation through compelling clinical study publications and endorsements from influential physicians; and
- brand and name recognition.

Competition could result in price-cutting, reduced profit margins and loss of market share, any of which could have a material adverse effect on our results of operations. In addition, our competitors with greater financial resources could acquire other companies that would enhance their name recognition and market share, and allow them to compete more effectively by bundling together related products. For example one competitor provides incentives for the purchase of its biopsy capital equipment and disposables when purchased with its digital mammography and stereotactic tables. Certain potential customers may view this value proposition as attractive, which could result in their decision not to purchase our products. We also anticipate that new products and improvements to existing products could be introduced that would compete with our current and future products. If we are unable to compete effectively, we will not be able to generate expected sales and our future financial performance will suffer.

Our ability to compete depends upon our ability to innovate, develop and commercialize new products and product enhancements.

The markets in which we compete involve rapid and substantial technological development and product innovations. There are few barriers to prevent new entrants or existing competitors from developing or acquiring products or technological improvements that compete effectively against our products or technology. If we are unable to innovate successfully to anticipate or respond to competitive threats, obtain regulatory approvals, or protect such innovation with defensible intellectual property, our revenues could fail to grow or could decline. Our business strategy is in part based upon our expectation that we will continue to make frequent new product introductions and improvements to existing products that will be demanded by our target customers. If we are unable to continue to develop new products and technologies as anticipated, our ability to grow and our future financial performance could be materially harmed. For example, we recently received 510(k) clearance from the FDA for our new SenoSonix System, an integration of Encor with ultra sound technology from Ultrasonix Medical Corporation of Canada. We have yet to commercially launch this product and there can be no assurances that we will be successful in obtaining meaningful revenues once it has been commercialized.

Our business strategy is heavily focused on integrated breast centers and other large institutions.

We are focusing our sales efforts on becoming a preferred provider to integrated breast centers and other large customer accounts. We cannot assure you that we will be able to secure or maintain these accounts or that this strategy will maximize our revenue growth. These targeted customers often have a rigorous and lengthy qualification process for approving new vendors and products. Additionally, breast centers are in many cases not located at one physical location, but instead involve the coordinated efforts of various geographically dispersed offices and physicians, which may complicate the qualification process and may strain our sales and support organizations. Further, these customers have not entered, and we do not expect them in the future to enter, long-term contracts to purchase our products. Therefore, obtaining approval from these potential customers to sell them our products may not result in significant or long-term sales of our products to them. Our strategy of focusing on large institutions may result in relatively few customers contributing a significant amount to our revenues. For example, Kaiser Permanente is our largest customer, and in the year ended December 31, 2006, and quarter ended September 30, 2007, represented approximately 7.6% and 5.2%, respectively, of our total revenues. We cannot assure you that Kaiser or other customer accounts will continue to purchase our products. The loss of any of these customers could have a material adverse impact on our results of operations.

Our strategy of providing a broad array of products to the breast care market may be difficult to achieve, given our size and limited resources.

We aim to be an attractive and convenient supplier for integrated breast centers by offering a broad product line of minimally invasive devices for breast care specialists. Commercializing several product lines simultaneously may be difficult because we are a relatively small company. Additionally, offering a broad product line will require us to manufacture, sell and support some products that are not as profitable or in as high demand as some of our other products, which could have a material adverse effect on our overall results of operations. To succeed in our approach, we will need to grow our organization considerably and enhance our relationships with third-party manufacturers and suppliers. If we fail to make product introductions successfully or in a timely manner because we lack resources, or if we fail to adequately manufacture, sell and support our existing products, our reputation may be negatively affected and our results of operations could be materially harmed.

We believe that demand for minimally invasive products for the diagnosis and treatment of breast cancer must grow in order for our business to grow as anticipated.

While there have been trends in recent years that favor increased screening, diagnosis and treatment of breast cancer, these trends may not continue. For example, the incidence of breast cancer in the United States appears to have fallen from its highest level over the last few years. Additionally, while the number of breast biopsies performed annually has increased significantly since 1997 when the American Cancer Society updated its guidelines for breast cancer screening, recommending that women should begin annual screening at age 40 rather than the previously recommended age 50, new

guidance could be published that could support a reversal of this trend. Some studies conclude that annual breast cancer screening by mammography for women under age 50 may be more harmful, due to increased radiation exposure, than beneficial. These factors, in addition to possible future innovations in screening technologies or in breast cancer treatment options, could result in a decline in breast biopsy procedures and radiation therapy, which could reduce our overall market.

We have limited sales and marketing experience and failure to build and manage our sales force or to market and distribute our products effectively could have a material adverse effect on our results of operations.

We rely on a direct sales force to sell our products. In order to meet our anticipated sales objectives, we expect to grow our sales organization significantly over the next several years. There are significant risks involved in building and managing our sales organization, including our ability to:

- hire and successfully integrate qualified individuals as needed;
- provide adequate training for the effective sale of our products; and
- retain and motivate our sales employees.

We expect that our Contura MLB Catheter will be a principal driver of future growth. However, our sales force historically has primarily sold diagnostic products and therefore has limited experience selling a therapeutic device. Our Contura MLB Catheter competes with products that are well-established. Accordingly, it is difficult for us to predict how well our sales force will perform.

Our failure to adequately address these risks could have a material adverse effect on our ability to sell our products, causing our revenues to be lower than expected and harming our results of operations.

We may be subject in the future to costly claims of infringement or misappropriation of the intellectual property rights of others, which could impact our business and harm our operations.

Our industry has been characterized by frequent demands for licenses and litigation. Our competitors, potential competitors or other patent holders may, in the future, assert that our products and the methods we employ are covered by their patents or misappropriate their intellectual property. In addition, we do not know whether our competitors will apply for and obtain patents that will prevent, limit or interfere with our ability to make, use, sell or import our products. Because patent applications may take years to issue, there may be applications now pending of which we are unaware that may later result in issued patents that our products infringe. There also could be existing patents that one or more components of our systems may inadvertently infringe. Although we may seek to settle any future claims, we may not be able to do so on reasonable terms, or at all. If we lose a claim against us, we may be ordered to pay substantial damages, including compensatory damages, which may be trebled in certain circumstances, plus prejudgment interest. We also could be enjoined, temporarily, preliminarily or permanently, from making, using, selling, offering to sell or importing our products or technologies essential to our products, which could significantly harm our business and operating performance.

We may become involved in litigation not only as a result of alleged infringement of a third party's intellectual property rights but also to protect our own intellectual property. Enforcing our patent rights against infringers, even when such litigation is resolved in our favor, could involve substantial costs and divert management's attention from our core business and harm our reputation.

If we are unable to obtain and maintain intellectual property protection covering our products, others may be able to make, use or sell our products, which could have a material adverse effect on our business and results of operations.

We rely on patent, copyright, trade secret and trademark laws and confidentiality agreements to protect our technology, products and our competitive position in the market. Additionally, our patent applications, including those covering our EnCor system, may not result in patents being issued to us or, if they are issued, may not be in a form that is advantageous to us. Any patents we obtain may be challenged or invalidated by third parties. Competitors also may design around our protected technology or develop their own technologies that fall outside our intellectual property rights. In addition, we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors, former employees or current employees, despite the existence of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we cannot be certain that the steps we have taken to protect our intellectual property will be effective or that any remedies we may have in these circumstances would be adequate. Moreover, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States.

We may not have adequate intellectual property protection for some of our products and products under development and consequently may need to obtain licenses from third parties. For example, we believe that we may need to obtain a third-party license related to our Guided Electrosurgical Dissection, or GED, device, which is currently under development. If we are unable to negotiate a license on terms acceptable to us, we may be unable to market our GED device unless we redesign it, which could have a material adverse effect on our future results of operations.

We are dependent on sole-source and single-source suppliers for certain of our products and components, thereby exposing us to supply interruptions that could have a material adverse effect on our business.

We have one product and several components of other products that we obtain from sole suppliers. We rely on one vendor for our Gamma Finder product, one vendor for our biopsy probe motors and one vendor for a biopsy probe coating. Other products and components come from single suppliers, but alternate suppliers are easier to identify. However, in many of these cases we have not yet qualified alternate suppliers and rely upon purchase orders, rather than longer-term supply agreements. We also do not carry a significant inventory of most components used in our products and generally could not replace our suppliers without significant effort and delay in production. In addition, switching components may require product redesign and new regulatory clearances by the FDA, either of which could significantly delay or prevent production and involve substantial costs.

Reliance on third-party vendors may lead to unanticipated interruptions in supply or failure to meet demand on a timely basis. Any supply interruption from our vendors or failure to obtain additional vendors for any of the components could limit our ability to manufacture our products and fulfill customer orders on a timely basis, which could harm our reputation and revenues.

We have limited experience manufacturing certain components of our products in significant quantities, which could adversely impact the rate at which we grow.

We may encounter difficulties in manufacturing relating to our products and products under development for the following reasons:

- our limited experience in manufacturing such products in significant quantities and in compliance with the FDA's Quality System Regulation;
- to increase our manufacturing output significantly, we will have to attract and retain qualified employees, who are in short supply, for the manufacturing, assembly and testing operations; and
- some of the components and materials that we use in our manufacturing operations are currently provided by sole and single sources of supply.

Our limited manufacturing experience has in the past resulted in unexpected and costly delays. For example, in 2006, as a part of our settlement of litigation with Suros Surgical Systems (now a wholly-owned subsidiary of Hologic), we implemented a redesign to the EnCor system cutter. This effort resulted in a short-term decrease in yields and a delay in implementing certain cost improvements, which had an adverse effect on our costs of goods sold. In addition, although we believe that our current manufacturing capabilities will be adequate to support our commercial manufacturing activities for the foreseeable future, we may be required to expand our manufacturing facilities if we experience faster-than-expected growth. If we are unable to provide customers with high-quality products in a timely manner, we may not be able to achieve wide market adoption for our EnCor system or other products and products under development. Our inability to successfully manufacture or commercialize our devices could have a material adverse effect on our product sales.

We rely on third-party manufacturers for certain components, and the loss of any of these manufacturers, or their inability to provide us with an adequate supply of high-quality components, could have a material adverse effect on our business.

Although we manufacture certain components and assemble some of our products at our corporate headquarters in Aliso Viejo, California, we rely on third parties to manufacture most of the components of our products and are in the process of transferring additional manufacturing and assembly to our Thailand contract manufacturer. Some of these relationships are new and we have not had experience with their large commercial-scale manufacturing capabilities. For example, since the end of 2005, we have been transferring a portion of our manufacturing operations to a third party in Thailand. Because of the distance between California and Thailand, we may have difficulty adequately supervising and supporting its operations. There are several risks inherent in relying on third-party manufacturers, including:

- failure to meet our requirements on a timely basis as demand grows for our products;
- errors in manufacturing components that could negatively affect the performance of our products, cause delays in shipment of our products, or lead to malfunctions or returns;
- inability to manufacture products to our quality specifications and strictly enforced regulatory requirements;
- inability to implement design modifications that we develop in the future;

- unwillingness to negotiate a long-term supply contract that meets our needs or to supply components on a short-term basis on commercially reasonable terms;
- prioritization of other customers orders over ours; and
- inability to fulfill our orders due to unforeseen events, including foreign political events, that result in a disruption of their operations.

If a manufacturer fails to meet our needs with high-quality products on a timely basis, we may be unable to meet customer demand, which could have a material adverse effect on our reputation and customer relationships.

Changes in coverage and reimbursement for procedures using our products could affect the adoption of our products and our future revenues.

Breast biopsy procedures and markers are typically reimbursed by third-party payors, including Medicare, Medicaid and private healthcare insurance companies. These payors may adversely change their coverage amounts and reimbursement policies. Also, healthcare reform legislation or regulation may be proposed or enacted in the future that adversely affects these policies and amounts. For example, the Federal Deficit Reduction Act of 2006 may in the future affect future reimbursement rates for our vacuum assisted biopsy products and Contura MLB Catheter products. We cannot assure you that the current scope of coverage or levels of reimbursement will continue to be available or that coverage of, or reimbursement for, our products will be available at all. If physicians, hospitals and other providers are unable to obtain adequate reimbursement for our current products or future products, or for the procedures in which such products are used, they may be less likely to purchase the products, which could have a material adverse impact on our market share.

Any acquisitions that we make could disrupt our business and have an adverse effect on our financial condition.

We expect that in the future we may identify and evaluate opportunities for strategic acquisitions of complementary product lines, technologies or companies. We may also consider joint ventures and other collaborative projects. However, we may not be able to identify appropriate acquisition candidates or strategic partners, or successfully negotiate, finance or integrate any businesses, products or technologies that we acquire. Furthermore, the integration of any acquisition and the management of any collaborative project may divert management's time and resources from our core business and disrupt our operations. We do not have any experience with acquiring other product lines, technologies or companies. We may spend time and money on projects that do not increase our revenues. Any cash acquisition we pursue would diminish the funds available to us for other uses, and any stock acquisition would be dilutive to our stockholders.

Our financial controls and procedures may not be sufficient to ensure timely and reliable reporting of financial information, which, as a public company, could materially harm our stock price and NASDAQ listing.

As a public company, we will require greater financial resources than we have had as a private company. We will need to hire additional employees for our finance department. We cannot provide you with assurance that our finance department has or will maintain adequate resources to ensure that we will not have any future material weakness in our system of internal controls. The effectiveness of our controls and procedures may in the future be limited by a variety of factors including:

- faulty human judgment and simple errors, omissions or mistakes;
- fraudulent action of an individual or collusion of two or more people;
- inappropriate management override of procedures; and
- the possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial information.

If we fail to have effective controls and procedures for financial reporting in place, we could be unable to provide timely and accurate financial information and be subject to NASDAQ delisting, SEC investigation, and civil or criminal sanctions.

Product liability claims may lead to expensive and time-consuming litigation, substantial damages, increased insurance rates, and may have a material adverse effect on our financial condition.

Our business exposes us to potential product liability claims that are inherent in the manufacturing, marketing and sale of medical devices. For example, in the past we experienced, and in the future could experience, an issue related to the tip of our Gel Mark Ultra Biopsy Site Marker shearing off in the patient's breast during the biopsy procedure, which could lead to a claim of damages, though none has previously been made. We may be unable to avoid product liability claims, including those based on manufacturing defects or claims that the use, misuse or failure of our products resulted in a misdiagnosis or harm to a patient. Although we believe that our liability coverage is adequate for our current needs, and while we intend to expand our product liability insurance coverage to any products we intend to commercialize, insurance may be unavailable,

prohibitively expensive or may not fully cover our potential liabilities. If we are unable to maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims, we may be unable to continue to market our products and to develop new products. Defending a product liability lawsuit could be costly and have a material adverse effect on our financial condition, as well as significantly divert management's attention from conducting our business. In addition, product liability claims, even if they are unsubstantiated, may damage our reputation by raising questions about our products' safety and efficacy, which could materially adversely affect our results of operations, interfere with our efforts to market our products and make it more difficult to obtain commercial relationships necessary to maintain our business.

We may be adversely affected by the impact of environmental and safety regulations.

We are subject to federal, state, local and foreign laws and regulations governing the protection of the environment and occupational health and safety, including laws regulating the disposal of hazardous wastes and the health and safety of our employees. We may be required to obtain permits from governmental authorities for certain operations. If we violate or fail to comply with these laws and regulations, we could incur fines, penalties or other sanctions, which could adversely affect our business and our financial condition and cause our stock price to decline. We also may incur material expenses in the future relating to compliance with future environmental laws. In addition, we could be held responsible for substantial costs and damages arising from any contamination at our present facilities or third-party waste disposal sites. We cannot completely eliminate the risk of contamination or injury resulting from hazardous materials, and we may incur material liability as a result of any contamination or injury.

Our success will depend on our ability to attract and retain key personnel, particularly members of management and scientific staff.

We believe our future success will depend upon our ability to attract and retain employees, including members of management, engineers and other highly skilled personnel. Our employees may terminate their employment with us at any time. Hiring qualified personnel may be difficult due to the limited number of qualified professionals and the fact that competition for these types of employees is intense. If we fail to attract and retain key personnel, we may not be able to execute our business plan.

We may be unsuccessful in our long-term goal of expanding our product offerings outside the United States and Canada.

For both the year ended December 31, 2006 and for the quarter ended September 30, 2007, we derived approximately 95% of our net revenues from sales within the United States and Canada. We have entered into distribution agreements with third parties outside the United States and Canada, but do not anticipate sales of our products through these distributors becoming a significant portion of our revenues in the foreseeable future. If we do begin to offer our products more broadly outside the United States and Canada, we expect that we will remain dependent on third-party distribution relationships and will need to attract additional distributors to increase the number of territories in which we sell our products. Distributors may not commit the necessary resources to market and sell our products to the level of our expectations. If current or future distributors do not perform adequately, or we are unable to locate distributors in particular geographic areas, our ability to realize long-term international revenue growth could be materially adversely affected.

Although some of our products have regulatory clearances and approvals from jurisdictions outside the United States and Canada, many do not. These products may not be sold in these jurisdictions until the required clearances and approvals are obtained. We cannot assure you that we will be able to obtain these clearances or approvals on a timely basis, or at all. In Japan, recent changes in the laws and regulations governing the approval process for medical devices has made it unlikely that we will be able to obtain approvals for our products within the foreseeable future.

Our ability to use net operating loss carryforwards may be limited.

Section 382 of the Internal Revenue Code generally imposes an annual limitation on the amount of net operating loss carryforwards that may be used to offset taxable income when a corporation has undergone significant changes in its stock ownership. We have internally reviewed the applicability of the annual limitations imposed by Section 382 caused by previous changes in our stock ownership and believe such limitations should not be significant. Future ownership changes, including changes resulting from or affected by our IPO, may adversely affect our ability to use our remaining net operating loss carryforwards. If our ability to use net operating loss carryforwards is limited, we may be subject to tax on our income earlier than we would otherwise be had we been able to fully utilize our net operating loss carryforwards.

Risks Related to Regulatory Matters

The FDA may find that we do not comply with regulatory requirements and take action against us.

Our products and facilities are subject to periodic unannounced inspections by the FDA and other regulatory bodies. In particular, we are required to comply with the FDA's Quality System Regulations, or QSRs, and other regulations, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, shipping and post-market surveillance of our products.

We underwent an inspection of our facilities by the FDA in April 2005, which resulted in the issuance in July 2005 of a Warning Letter from the FDA related to, among other things, our failure to adequately validate manufacturing changes we undertook to prevent the tip of the Gel Mark Ultra Biopsy Site Marker from shearing off in the patient's breast during the biopsy procedure, which we had experienced. The letter required us to take prompt action to strengthen our Quality System and product engineering area. We responded to the FDA with a comprehensive corrective action plan in August 2005. We believe we are in compliance with the QSRs. However, during a future inspection, the FDA may determine that we have failed to adequately or completely implement the corrective action plan or may find additional material violations. Such a determination could lead the FDA to commence an enforcement action against us, which may include the following sanctions:

- injunctions, fines, other civil penalties or additional Warning Letters;
- the refusal of, or delay by, the FDA in granting further 510(k) clearances or approving further premarket approval applications;
- suspension or withdrawal of our FDA clearances or approvals;
- operating restrictions, including total or partial suspension of production, distribution, sales and marketing of our products; or
- product recalls, product seizures or criminal prosecution of our company, our officers or our employees.

Any of these could have a material adverse effect on our reputation, results of operation and financial condition.

If we fail to obtain or maintain necessary FDA clearances or approvals for products, or if clearances or approvals are delayed, we will be unable to commercially distribute and market our products in the United States.

Our products are medical devices, and as such are subject to extensive regulation in the United States and in the foreign countries where we do business. Unless an exemption applies, each medical device that we wish to market in the United States must first receive 510(k) clearance or premarket approval from the FDA. Either process can be lengthy and expensive. The FDA's 510(k) clearance process usually takes from three to twelve months from the date the application is complete, but it may take longer. The premarket approval process is much more costly, lengthy and uncertain. It generally takes from one to three years from the date the application is completed or even longer. Achieving a completed application is a process that may require numerous clinical trials and the filing of amendments over time. We expect that our products in the foreseeable future will be subject to 510(k) procedures and not premarket approval, or PMA, applications. We may not be able to obtain additional FDA clearances or approvals in a timely fashion, or at all. Delays in obtaining clearances or approvals could adversely affect our revenues and profitability.

Modifications to our devices may require new 510(k) clearances, which may not be obtained.

The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new clearance; however, the FDA can review a manufacturer's decision. Any modifications to an FDA-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use would require a 510(k) clearance or possibly a premarket approval.

We have modified aspects of some of our products since receiving FDA clearance, but we believe that new 510(k) clearances are not required. We may make additional modifications, and in appropriate circumstances, determine that new clearance or approval is unnecessary. The FDA may not agree with our decisions not to seek new clearances or approvals. If the FDA requires us to seek 510(k) clearances or approval for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain clearance or approval. Also, in these circumstances we may be subject to adverse publicity, regulatory Warning Letters and significant fines and penalties.

Government regulation imposes significant restrictions and costs on the development and commercialization of our products.

Any products cleared or approved by the FDA are subject to on-going regulation. Any discovery of previously unknown or unrecognized problems with the product or a failure of the product to comply with any applicable regulatory requirements can result in, among other things:

- Warning Letters, injunctions, fines or other civil penalties;
- the refusal of, or delay by, the FDA in granting further 510(k) clearances or approving further premarket approval applications;
- suspension or withdrawal of our FDA clearances or approvals;
- operating restrictions, including total or partial suspension of production, distribution, sales and marketing of our products; or
- product recalls, product seizures or criminal prosecution of our company, our officers or our employees.

Any of these could have a material adverse effect on our reputation and results of operations.

Risks Related to the Securities Markets and Ownership of Our Common Stock

Our common stock has been publicly traded for a short time and an active trading market may not be sustained.

Prior to March 2007, there had been no public market for our common stock. An active trading market may not be sustained. The lack of an active market may impair the value of your shares and your ability to sell your shares at the time you wish to sell them. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other companies, products or technologies by using our shares as consideration.

If our public guidance or our future operating performance does not meet investor expectations, our stock price could decline.

As a public company, we provide guidance to the investing community regarding our anticipated future operating performance. Our business typically has a short sales cycle, so that we do not have significant backlog of orders at the start of a quarter, and our ability to sell our products successfully is subject to many uncertainties. In light of these factors, it is difficult for us to estimate with accuracy our future results. Our expectations regarding these results will be subject to numerous risks and uncertainties that could make actual results differ materially from those anticipated. If our actual results do not meet our public guidance or our guidance or actual results do not meet the expectations of third-party financial analysts, our stock price could decline significantly.

We expect that the price of our common stock will fluctuate substantially.

The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:

- volume and timing of sales of our products;
- the introduction of new products or product enhancements by us or our competitors;
- disputes or other developments with respect to our intellectual property rights or the intellectual property rights of others;
- our ability to develop, obtain regulatory clearance or approval for, and market, new and enhanced products on a timely basis;
- product liability claims or other litigation;
- quarterly variations in our or our competitors' results of operations;
- sales of large blocks of our common stock, including sales by our executive officers and directors;
- announcements of technological or medical innovations for the diagnosis and treatment of breast cancer;
- changes in governmental regulations or in the status of our regulatory approvals or applications;
- changes in the availability of third-party reimbursement in the United States or other countries;
- changes in earnings estimates or recommendations by securities analysts; and

- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

These and other factors may make the price of our stock volatile and subject to unexpected fluctuation.

Our directors, executive officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

Our officers, directors and principal stockholders that currently hold more than 5% of our common stock together control nearly a majority of our outstanding common stock. As a result, these stockholders, if they act together, will be able to exercise significant influence over the management and affairs of our company and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control, might have a material adverse effect on the market price of our common stock and may not be in the best interest of our other stockholders.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

As of September 30, 2007, approximately 10,782,635 shares of common stock have become eligible for sale following the expiration of lock-up arrangements with our stockholders that we had previously entered into in connection with our IPO. If our stockholders sell substantial amounts of our common stock in the public, the market price of our common stock could decline.

Our Amended and Restated Certificate of Incorporation and Bylaws, and Delaware law, contain provisions that could discourage a takeover.

Our Amended and Restated Certificate of Incorporation and Bylaws, and Delaware law, contain provisions that might enable our management to resist a takeover, and might make it more difficult for an investor to acquire a substantial block of our common stock. These provisions include:

- a classified board of directors;
- advance notice requirements to stockholders for matters to be brought at stockholder meetings;
- a supermajority stockholder vote requirement for amending certain provisions of our Amended and Restated Certificate of Incorporation and Bylaws;
- limitations on stockholder actions by written consent; and
- the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer.

These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of our common stock and limit the price that investors might be willing to pay in the future for shares of the common stock.

We do not intend to pay cash dividends.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, the terms of any future debt or credit facility may preclude us from paying any dividends. As a result, we anticipate that capital appreciation of our common stock, if any, will be your sole source of potential gain for the foreseeable future.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

We did not sell any unregistered equity securities during the period covered by this report.

We registered for the initial public offering of our common stock, par value $0.001 per share, on a Registration Statement on Form S-1 (Registration No. 333-134466), which was declared effective on March 28, 2007. On April 3, 2007 we completed the initial public offering of our common stock by selling 5.5 million shares at $8.00 per share. Additionally, on April 20, 2007, the underwriters in the IPO exercised their overallotment option to purchase an additional 825,000 shares at $8.00 per share. Gross proceeds from the offering were $50.6 million. Total expenses from the offering were $5.8 million, which included underwriting discounts and commissions of $3.5 million, and $2.3 million in other offering-related expenses. Net offering proceeds, after deducting total expenses were $44.8 million.

Of the $44.8 million in net proceeds, through September 30, 2007, we have spent approximately $1.8 million to repay interest owing on our May 2006 Notes, the repayment of which accelerated and became due as a result of the IPO. For the period from the IPO through September 30, 2007, we incurred $8.8 million in selling and marketing expenses, $3.2 million in research and development expenses and $2.3 million in general and administrative expenses.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit No.	Description
3.2*	Amended and Restated Certificate of Incorporation.
3.4*	Bylaws.
4.1*	Specimen Common Stock Certificate.
4.2*	Fourth Amended and Restated Investors' Rights Agreement, dated May 3, 2006, by and among the Registrant and certain stockholders.
31.1	Certification of Chief Executive Officer under Securities Exchange Act Rule 13a-14(a).
31.2	Certification of Chief Financial Officer under Securities Exchange Act Rule 13a-14(a).
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S. C. 1350 and Securities Exchange Act Rule 13a-14(b).

* Incorporated by reference from our Registration Statement on Form S-1 (Registration No. 333-134466), which was declared effective on March 28, 2007.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 13, 2007

/s/ Lloyd H. Malchow
Lloyd H. Malchow
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2007

/s/ Kevin J. Cousins
Kevin J. Cousins
Chief Financial Officer
(Principal Financial and Accounting Officer)

Table of Contents

INDEX TO EXHIBITS

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32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S. C. 1350 and Securities Exchange Act Rule 13a-14(b).

* Incorporated by reference from our Registration Statement on Form S-1 (Registration No. 333-134466), which was declared effective on March 28, 2007.

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Lloyd H. Malchow, certify that:

1. I have reviewed this quarterly report on Form 10-Q of SenoRx, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2007

/s/ Lloyd H. Malchow
Lloyd H. Malchow
President and Chief Executive Officer

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kevin J. Cousins, certify that:

1. I have reviewed this quarterly report on Form 10-Q of SenoRx, Inc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2007

/s/ Kevin J. Cousins
Kevin J. Cousins
Chief Financial Officer

 Exhibit 32.1

CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Lloyd H. Malchow, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of SenoRx, Inc. on Form 10-Q for the quarterly period ended September 30, 2007 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of SenoRx, Inc.

Date: November 13, 2007

By: /s/ Lloyd H. Malchow
Name: Lloyd H. Malchow
Title: President and Chief Executive Officer

I, Kevin J. Cousins, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of SenoRx, Inc. on Form 10-Q for the quarterly period ended September 30, 2007 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of SenoRx, Inc.

Date: November 13, 2007

By: /s/ Kevin J. Cousins
Name: Kevin J. Cousins
Title: Chief Financial Officer

Exhibit UU

US005931774A

United States Patent [19]

Williams et al.

[11] **Patent Number: 5,931,774**

[45] **Date of Patent: Aug. 3, 1999**

[54] **INFLATABLE DEVICES FOR TUMOR TREATMENT**

[75] Inventors: **Jeffery A. Williams**, Baltimore, Md.; **Christopher H. Porter**, Woodinville, Wash.; **Mark A. Rydell**, Golden Valley, Minn.

[73] Assignee: **Proxima Therapeutics, Inc.**, Alpharetta, Ga.

[21] Appl. No.: **08/727,259**

[22] Filed: **Oct. 7, 1996**

Related U.S. Application Data

[63] Continuation-in-part of application No. 08/307,165, Sep. 14, 1994, Pat. No. 5,611,767, which is a continuation of application No. 07/715,923, Jun. 14, 1991, Pat. No. 5,429,582.

[51] **Int. Cl.**[6] **A61N 5/02**

[52] **U.S. Cl.** **600/2**

[58] **Field of Search** 600/1–8; 604/19–20; 607/1–3, 88, 96, 99, 100, 103, 105, 107, 113, 114

[56] **References Cited**

U.S. PATENT DOCUMENTS

2,043,630	6/1936	Raiche	18/58
2,677,375	5/1954	Raiche	128/349
3,173,418	3/1965	Baran	128/351
3,324,847	6/1967	Zoumboulis	128/1.2
3,640,269	2/1972	Delgado	128/2
3,831,629	8/1974	Mackal et al.	137/525
3,872,856	3/1975	Clayton	128/1.2
4,022,190	5/1977	Meyer	128/2 A
4,085,757	4/1978	Pevsner	604/96
4,103,689	8/1978	Leighton	128/350 V
4,133,315	1/1979	Berman et al.	604/96
4,206,762	6/1980	Cosman	128/660
4,213,461	7/1980	Pevsner	128/348
4,217,889	8/1980	Radovan et al.	128/1
4,281,667	8/1981	Cosman	128/348
4,292,960	10/1981	Paglione	128/1.1
4,382,445	5/1983	Sommers	604/8
4,417,576	11/1983	Baran	128/207.15
4,541,429	9/1985	Prosl et al.	604/249

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

0 205 384	12/1986	European Pat. Off. .
0 340 881	11/1989	European Pat. Off. .
0 366 814	5/1990	European Pat. Off. .
37 25 691	3/1988	Germany .
2 105 201	3/1983	United Kingdom .

(List continued on next page.)

OTHER PUBLICATIONS

Exhibit A—catalog page of American Heyer–Schulte.

Garfield, et al., "Postoperative intracavitary chemotherapy of malignant glimos", *J. Neurosurg.*, vol. 39, Sep., 1973, pp. 315–322.

NASA Tech Briefs, Jun., 1990, at p. 106.

Shimm et al., "Scanned Focessed Ultrasound Hyperthermia: Initial Crucial Results", *Int. J. Radiation Oncology Bio. Phys.*, Nov. 1988, vol. 15, pp. 1203–1208.

Roberts et al., "Interstitial hyperthermia and iridium brachytherapy in treatment of malignant gliomas" *J. Neorosurg.*, vol. 64, Apr. 1986.

(List continued on next page.)

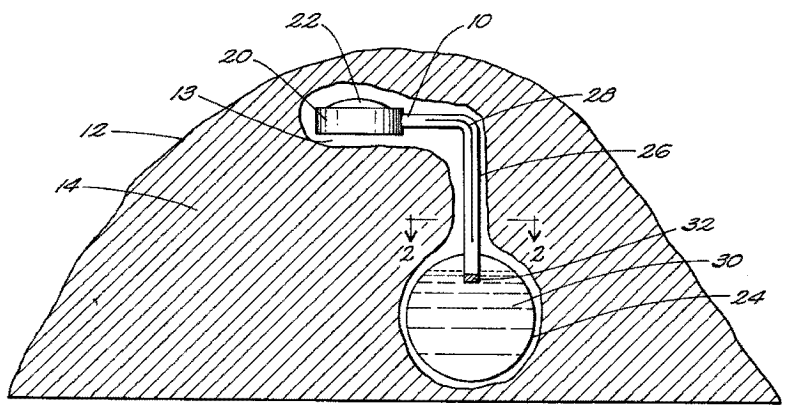
Primary Examiner—John P. Lacyk

Attorney, Agent, or Firm—Thomas J. Engellenner; Nutter, McClennen & Fish,LLP

[57] **ABSTRACT**

Implantable devices for treatment of proliferative disorders are described. In one aspect, the invention provides an implantable apparatus for treating a proliferative disorder in a patient. The device comprises a treatment fluid receptacle for receiving a treatment fluid, an inflatable balloon having a balloon body, a catheter connected between the treatment fluid receptacle and the balloon and defining a fluid flow path therebetween, and a diffusion barrier disposed in the fluid flow path between the treatment fluid receptacle and the balloon. Methods for treating proliferative disorders with the devices are also disclosed.

43 Claims, 2 Drawing Sheets



U.S. PATENT DOCUMENTS

4,558,693	12/1985	Lash et al.	128/79
4,564,022	1/1986	Rosenfeld et al.	128/748
4,588,394	5/1986	Schulte et al.	604/9
4,593,703	6/1986	Cosman	128/748
4,601,713	7/1986	Fuqua	604/280
4,602,655	7/1986	Mackal	137/515
4,617,015	10/1986	Foltz	604/100
4,619,247	10/1986	Inoue et al.	128/6
4,653,508	3/1987	Cosman	128/748
4,655,745	4/1987	Corbett	604/49
4,655,748	4/1987	Mushika	604/96
4,660,568	4/1987	Cosman	128/748
4,681,132	7/1987	Lardner	137/271
4,681,560	7/1987	Schulte et al.	604/9
4,699,615	10/1987	Fischell et al.	604/131
4,706,652	11/1987	Horowitz	128/1.2
4,710,177	12/1987	Smith et al.	604/185
4,754,745	7/1988	Horowitz	128/1.2
4,754,752	7/1988	Ginsburg et al.	128/303.12
4,763,642	8/1988	Horowitz	128/1.2
4,776,369	10/1988	Lardner et al.	137/515.5
4,788,063	11/1988	Fisher et al.	424/449
4,800,899	1/1989	Elliott	600/2
4,816,016	3/1989	Schulte et al.	604/9
4,821,725	4/1989	Azam et al.	128/420
4,846,191	7/1989	Brockway et al.	128/748
4,867,741	9/1989	Portnoy	604/10
5,084,015	1/1992	Moriuchi	604/96
5,106,360	4/1992	Ishiwara et al.	600/2
5,112,303	5/1992	Pudenz et al.	604/49
5,125,888	6/1992	Howard et al.	600/12
5,152,747	10/1992	Olivier	604/93
5,236,410	8/1993	Granov et al.	600/12
5,429,582	7/1995	Williams	600/2

FOREIGN PATENT DOCUMENTS

WO 90 04365	5/1990	WIPO .
WO 91 05528	5/1991	WIPO .
WO 92 10932	7/1992	WIPO .
92/22350	12/1992	WIPO .
WO 93 09724	5/1993	WIPO .

OTHER PUBLICATIONS

Chun et al., "Interstitial iridum–192 implantation for malignant brain tumours Part II", *The British Journal of Radiology*, Feb., 1989, pp. 158–162.

Am. J. Clin. Oncol., (CCT), vol. 10, No. 2, 1987, at p. 106, item (13).

Gutin et al. "Brachytherapy of recurrent malignant brain tumors with removable high–activity iodine–125 sources", *J. Neurosurg*, vol. 60, pp. 61–68, Jan. 1984.

Wu et al., "Interstitial iridium–192 implantation for malignant brain tumours Part I", *The British Journal of Radiology*, pp. 154–157, Feb. 1989.

Raaphorst et al. "A Comparison of Heat and Radiation Sensitivity of Three Human Glioma Cell Lines", *J. Radiation Oncology Biol. Phys.*, vol. 17, pp. 615–622.

Moidel et al., "Materials for Selective Tissue Heating in a Radiofrequency Electromagnetic Field for the Combined Chemothermal Treatment of Brain Tumors", *J. Biomed Mater. Res.*, vol. 10, pp. 327–334, 1976.

Exhibit B—Brochure of Halkey–Roberts Corporation of St. Petersburg, Florida.

European Search Report Application No. EP 92 91 3085 dated Dec. 12, 1995.

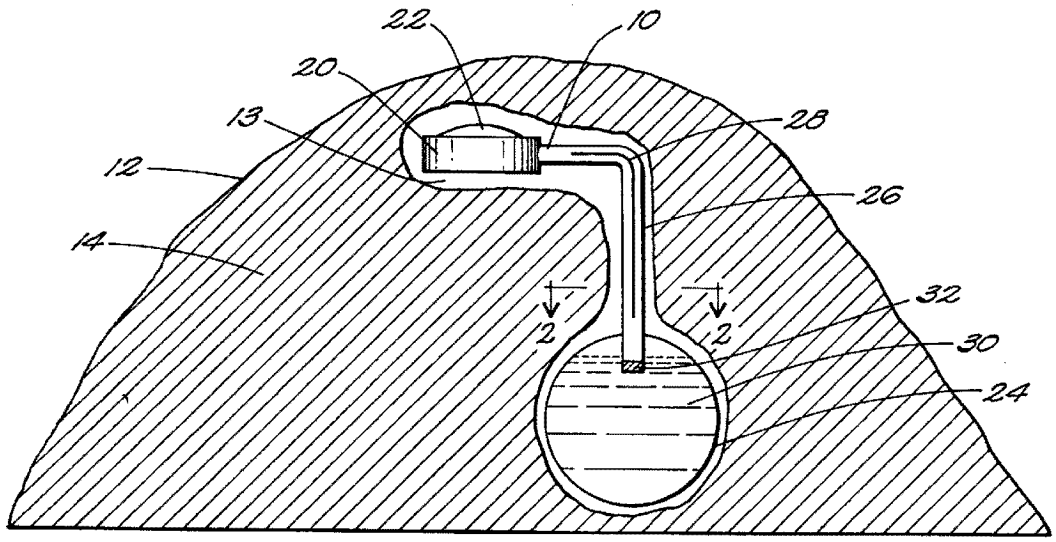


FIG. 1

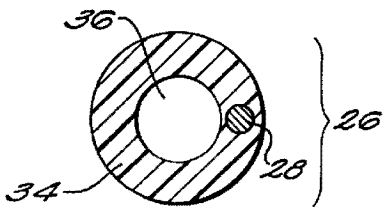


FIG. 2A

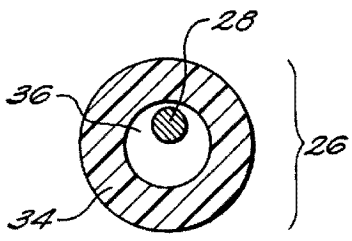


FIG. 2B

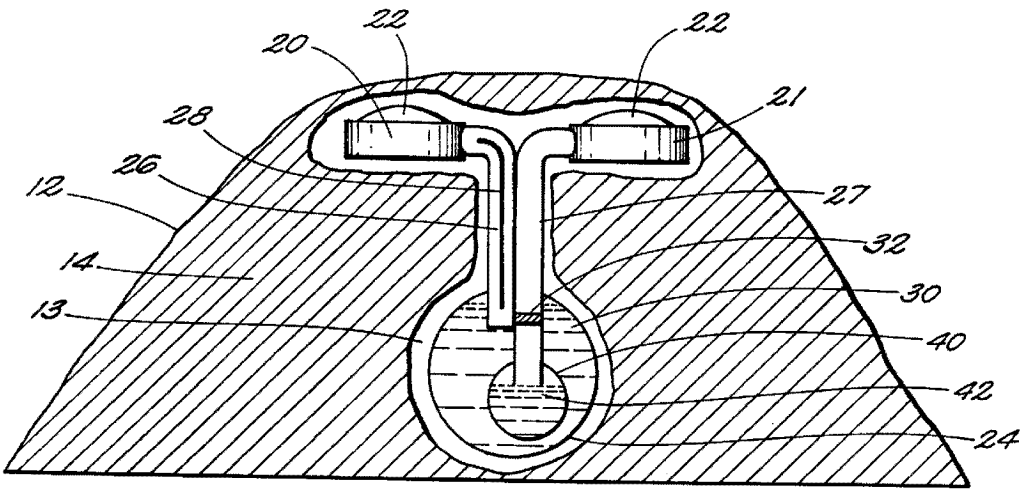


FIG. 3

INFLATABLE DEVICES FOR TUMOR TREATMENT

RELATED APPLICATIONS

This application is a continuation-in-part of U.S. Ser. No. 08/307,165, filed Sep. 14, 1994, now U.S. Pat. No. 5,611,767, which is a continuation of U.S. Ser. No. 07/715,923, filed Jun. 14, 1991, now U.S. Pat. No. 5,429,582, the contents of which are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

Treatment of proliferative disorders has become increasingly sophisticated in recent years, and improvements in surgical, chemotherapeutic and brachytherapeutic techniques have led to better outcomes in patients suffering from such disorders. The need for improved devices for administration of chemotherapy and brachytherapy has resulted in a number of new devices capable of delivering one or more treatments to proliferative disease sites, such as tumors. One such device is described in U.S. Pat. No. 5,429,582 to Williams, which discloses an inflatable device for multimodal therapy of tumors. Nevertheless, improved devices for treatment of proliferative disorders are needed.

SUMMARY

This invention provides improved devices for the treatment of tumors and other proliferative disorders in a patient in need of such treatment, and methods of treating proliferative disorders using such devices.

In one aspect, the invention provides an implantable apparatus for treating a proliferative disorder in a patient. The device comprises a treatment fluid receptacle for receiving a treatment fluid, an inflatable balloon having a balloon body, a catheter connected between the treatment fluid receptacle and the balloon and defining a fluid flow path therebetween, and a diffusion barrier disposed in the fluid flow path between the treatment fluid receptacle and the balloon.

In certain embodiments, the treatment fluid receptacle has a small volume and is adapted to be implanted subcutaneously in the body of the patient. In certain embodiments, the device further includes a malleable element. In certain embodiments, the diffusion barrier is a narrow flow segment. In certain embodiments, the balloon has a substantially spherical shape when inflated. In other embodiments, the balloon has a substantially ovoid shape when inflated. In some embodiments, the balloon is secured to the catheter at substantially a single point on the balloon body. In other embodiments, the balloon is secured to the catheter at a plurality of points on the balloon body. In certain embodiments, the balloon has an irregular shape when inflated.

The balloon body can be substantially impermeable to the treatment fluid, while in other embodiments, the balloon can comprise a semipermeable membrane. In certain embodiments, the treatment fluid receptacle can be flushed with a flushing fluid without substantially expanding the balloon. In some embodiments, the balloon is secured to the catheter such that the balloon maintains a pre-selected shape during inflation. In preferred embodiments, the malleable element, if present, does not interfere with NMR measurements.

In certain embodiments, the balloon comprises a double-walled balloon or a triple-walled balloon. In some embodiments, the proliferative disorder is a brain tumor. In

certain embodiments, the balloon is adapted for placement in a cavity left by surgical removal of a tumor from the patient. In other embodiments, the balloon is adapted for placement in a natural body cavity. In preferred embodiments, the balloon is filled with a treatment fluid. In certain embodiments, the treatment fluid is a radioactive fluid. In some embodiments, the treatment fluid has substantially physiological tonicity.

In certain embodiments, the apparatus further comprises a second treatment fluid receptacle. In certain embodiments, the second treatment fluid receptacle fluidly communicates with a volume between inner and outer balloon walls.

In another embodiment, the invention provides an implantable apparatus for treating a proliferative disorder in a patient. The implantable apparatus includes a treatment fluid receptacle for receiving a treatment fluid, an inflatable balloon having a balloon body; a catheter connected between the treatment fluid receptacle and the balloon and defining a fluid flow path therebetween; and a diffusion barrier disposed in the fluid flow path between the treatment fluid receptacle and the balloon, and in which the balloon is secured to the catheter such that the balloon maintains a pre-selected shape during inflation; and in which the treatment fluid receptacle is adapted to be flushed with a small volume of a flush fluid.

In another aspect, the invention provides a method for treating a proliferative disorder, such as a tumor, in a patient. The method includes the steps of implanting in the patient's body an inflatable treatment apparatus, in which the apparatus includes a treatment fluid receptacle for receiving a treatment fluid; an inflatable balloon having a balloon body; a catheter connected between the treatment fluid receptacle and the balloon and defining a fluid flow path therebetween; and a diffusion barrier disposed in the fluid flow path between the treatment fluid receptacle and the balloon; and introducing a treatment fluid into the treatment fluid receptacle such that the balloon is inflated; such that the proliferative disorder is treated.

In certain embodiments, the method includes the further step of flushing the treatment fluid into the balloon.

In another aspect, the invention provides a method for treating a proliferative disorder in a patient. The method comprises determining a characteristic of a cavity in the patient's body, the characteristic being selected from the group consisting of volume, shape, or a dimension; selecting an inflatable balloon suitable for placement in the cavity, the balloon including a balloon body. The method includes the further steps of implanting in the cavity an inflatable treatment apparatus comprising a treatment fluid receptacle for receiving a treatment fluid; the inflatable balloon; a catheter connected between the treatment fluid receptacle and the balloon and defining a fluid flow path therebetween; and a diffusion barrier disposed in the fluid flow path between the treatment fluid receptacle and the balloon. The method further includes the step of introducing a treatment fluid into the treatment fluid receptacle such that the balloon is inflated, such that the proliferative disorder is treated.

In certain embodiments, the method includes, prior to the implanting step, the further step of assembling the inflatable treatment apparatus.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic cross-sectional view of one embodiment of the treatment devices of the invention.

FIGS. **2**A and **2**B show cross-sectional views along the line **2**—**2**' of embodiments of the catheter of the invention.

FIG. **3** is a schematic cross-sectional view of a double-balloon embodiment of a treatment device of the invention.

DETAILED DESCRIPTION OF THE INVENTION

The ability to selectively deliver therapy to a target organ or site, e.g., a tumor, is of great value to physicians. Accordingly, the invention provides methods and apparatuses suitable for delivery of one or more therapeutic modalities in a selective fashion.

For convenience, certain terms employed in the specification, examples, and appended claims are collected here.

The term "proliferative disorder" is recognized in the art, and, as used herein, refers to a disorder including or characterized by rapid or abnormal cell growth or proliferation. Exemplary proliferative disorders include, but are not limited to, tumors, e.g., cancerous tumors; restenosis, e.g., regrowth of smooth muscle cells of blood vessels after angioplasty; abnormal angiogenesis; hyperplasia, e.g., benign prostatic hyperplasia; and the like.

The term "treatment fluid," as used herein, refers to a fluid used for therapy of a proliferative disorder. Treatment fluids include chemotherapy fluids such as are conventional in the art, as well as fluids suitable for radiation therapy (brachytherapy), e.g., fluids comprising a radioisotope useful in treatment of proliferative disorders.

The term "treatment fluid receptacle," as used herein, refers to a receptacle or chamber adapted for receiving a treatment fluid. Treatment fluid receptacles are known in the art, and include injection ports and similar devices. A "small-volume" treatment fluid receptacle has a volume or hold-up less than conventional treatment fluid receptacles, e.g., less than about 5 ml, more preferably less than about 2 ml, and still more preferably less than 1.5 ml. Thus, treatment fluid receptacles having little dead space or low hold-up volumes are generally preferred for use in the methods and devices of the invention. Particularly preferred treatment fluid receptacles can be flushed with a small volume of flush fluid, as described in more detail below.

The term "diffusion barrier," as used herein, refers to an element adapted for decreasing or preventing diffusion or flow of fluid from a balloon into the catheter lumen or treatment fluid receptacle of the subject inflatable treatment device.

A balloon that maintains a "substantially constant shape," as used herein, refers to a balloon that maintains substantially a single shape or profile over a range of inflation sizes. Thus, for example, a balloon that maintains a substantially spherical shape upon inflation has a generally spherical shape over a range of inflation sizes, from low inflation to full inflation, and does not generally change shape as inflation is increased or decreased. It will be understood by the skilled artisan, however, that the initial shape of a balloon can be chosen to minimize the size or profile of the deflated balloon, e.g., to ease insertion of the balloon into a body cavity. Thus, a balloon can have an initial shape different from a "substantially constant shape," and still assume a "constant shape" after partial inflation. A "predetermined shape" refers to a shape that can be selected by the practitioner before balloon insertion, e.g., a shape chosen to ensure compliance of the balloon body to a selected surface, e.g., a cavity surface.

The term "narrow flow segment", as used herein, refers to a narrowed or restricted portion of a flow path. Preferably, a narrow flow segment has a flow passage sufficiently small to slow or prevent significant flow or diffusion of a fluid through the passage without application of pressure.

The term "malleable element," as used herein, refers to an element, e.g., a wire, that is malleable or flexible, i.e., capable of being shaped by bending, flexing, pressing and the like, and maintaining, temporarily or permanently, the shape thus provided. In preferred embodiments, a malleable element can be shaped by hand, e.g., by a surgeon performing a surgical procedure, to impart a selected shape to the malleable element and to the catheter of which it forms a part.

The term "flushing fluid," as used herein, refers to fluid that can be used to flush, rinse, or wash a flow portion of an inflatable treatment device. A flushing fluid can be inert, e.g., a saline solution, or can itself be a treatment fluid. In general, an inert flushing fluid is preferred.

The term "patient," as used herein, refers to an animal in need of treatment for, or susceptible to, a proliferative disorder. In preferred embodiments, the patient is a warm-blooded animal, more preferably a mammal, including humans and non-human mammals such as dogs, cats, pigs, cows, sheep, goats, rats, and mice. In a particularly preferred embodiment, the subject is a human.

The inflatable treatment devices of the invention provide certain advantages over devices known in the art. The subject devices are adaptable to a wide variety of therapeutic treatments, and are simple and safe to use. In general, the devices are implanted in a patient's body such that the balloon is in close proximity to the site to be treated, e.g., the tumor, blood vessel, and the like. In one embodiment, the balloon is placed in a natural body cavity or a cavity resulting from surgical removal or displacement of tissue, e.g., surgical debulking of at least a portion of a tumor, or angioplasty to displace or compress a growth of a blood vessel.

Thus, for example, FIG. **1** shows a cross-sectional view of an inflatable device of the invention when implanted in a body cavity. In this embodiment, the device **10** is implanted below the skin **12** in a cavity **13** formed in the patient's tissue **14**. The device **10** includes an injection port **20** which has an elastomeric seal **22** secured thereto. A balloon **24** is disposed in the cavity **13** and fluidly connected to the injection port **20** through a catheter **26**, which includes a malleable element **28**. The balloon is filled with a treatment fluid **30**, which fluid is prevented from flowing back from the balloon **24** into the catheter **26** by a diffusion barrier **32**.

In certain embodiments, a treatment fluid receptacle is implanted subcutaneously, permitting ready injection of a treatment fluid while allowing healing of a surgical incision. Treatment fluid receptacles suitable for use in the devices of the invention are known in the art. For example, injection ports, which can be subcutaneously implanted, have been described in, e.g., U.S. Pat. Nos. 4,816,016 and 4,681,560 to Schulte, and are commercially available (e.g., from C. R. Bard Co.). An injection port for implantation in vivo should be constructed of materials that will not provoke an immune response or tissue reaction. An injection port preferably has an elastomeric seal secured to a base and defining an injection chamber of predetermined volume. The elastomeric seal can be adapted to sealingly engage a needle that pierces the seal, e.g., a hypodermic needle, and to reseal when the needle is removed, thereby preventing leakage. In general, preferred treatment fluid receptacles can be readily and efficiently flushed with a small volume of flush fluid, e.g., can be flushed with less than about 5 ml of flush fluid, more preferably less than about 2 ml, and still more pref-

erably less than 1.5 ml. The amount of flush fluid required will be determined, at least in part, by such factors as the total volume of the treatment fluid receptacle, the amount of "dead space" in the treatment fluid receptacle, the nature of the treatment fluid and the flush fluid, and the like. In preferred embodiments, the volume of the treatment fluid receptacle, e.g., the injection chamber, is minimized, e.g., has a small volume. By providing a small-volume treatment fluid receptacle, the volume of treatment and flushing fluids is minimized, preventing overinflation of the balloon and decreasing the volume of fluids that must be handled by the physician. Preferred treatment fluid receptacles have a volume of at least 0.5 ml, but not more than 5 ml, more preferably between about 1 and about 3 ml. In general, it is desirable for the injection port to be palpable through the skin, so that it can be easily located. The treatment fluid receptacle can be at least partially opaque to X-rays, permitting localization by radiography.

As mentioned above, in certain embodiments it is desirable, after treatment fluid has been injected into the treatment device, to flush the injection port to displace a treatment fluid from the injection port and catheter. For example, when the treatment fluid is a radioactive fluid, it is desirable to prevent radiation damage to healthy tissue adjacent to the treatment fluid receptacle and along the catheter path. To prevent damage to healthy tissue, the treatment fluid can be flushed out of the injection port and away from such tissue. The flush fluid can be flushed through the catheter and into the balloon, thereby flushing the catheter and increasing the amount of radioactive material in the balloon. A small-volume treatment fluid receptacle can be flushed rapidly and completely using small volumes of flush solution, thereby reducing the amount of additional fluid added to the balloon. Thus, a small-volume treatment fluid receptacle is preferred for use with radioactive treatment fluids. Alternatively, the flush fluid can be removed from the treatment device, e.g., by use of a needle, positioned in the injection port, for withdrawing excess fluid. In this embodiment, two needles can be employed simultaneously: one needle for injection of a flush fluid into the injection port, and a second needle for removal of the fluid. In this embodiment, further inflation of the balloon can be prevented.

The inventive devices can include a diffusion barrier, to prevent unwanted backflow of treatment fluid from the balloon into the catheter. The diffusion barrier thereby prevents premature deflation of the balloon and isolates the treatment fluid in the balloon. In particular, the diffusion barrier can reduce or prevent diffusion or flow of a treatment fluid, especially a radioactive treatment fluid, from the balloon into the catheter or other parts of the implantable device, thereby preventing damage to healthy tissue adjacent to the catheter track. The diffusion barrier can be any element or elements adapted to retard or prevent fluid flow, including, without limitation, a valve (e.g., a check valve) or other flow regulating element, a narrow flow segment, and the like. A valve can be manually or automatically operated to permit control of fluid flow, if desired, e.g., during balloon filling, flushing of an injection port, or removal of fluid from the device. In certain embodiments, the diffusion barrier is an elastomeric material disposed in the fluid flow path and having a slit, e.g., a slit of proportions similar to a Holter valve opening. In this embodiment, fluid flow through the diffusion barrier can be accomplished by the application of fluid under pressure, e.g., by providing a fluid under pressure with a hypodermic syringe, causing the elastomer to yield sufficiently to permit fluid flow. Preferably, the pressure required to cause fluid flow through the diffusion barrier is not so high as to present risk of rupture of the therapeutic device, but is sufficient to reduce unwanted flow from the balloon. The diffusion barrier can provide resistance to fluid flow in one direction (e.g., a one-way check valve) or in both directions. However, the diffusion barrier is preferably adapted to allow removal of fluid from the balloon when the therapeutic procedure is complete, preferably without requiring removal of the balloon from the body cavity. Thus, in certain embodiments, the diffusion barrier is not a check valve. The diffusion barrier can reduce or eliminate flow from the balloon for at least a short period of time, e.g., sufficient time for therapeutic treatment to be completed.

In certain embodiments, the inventive apparatus can include a malleable element extending through at least a portion of the length of the catheter lumen. Thus, the malleable element is preferably adapted to confer a shape upon at least a portion of the catheter length. The malleable element is preferably an integral component of the catheter, and is not a stylet or guidewire. The malleable element can provide increased stiffness to the catheter, thereby preventing kinking of the catheter and concomitant blockage of the lumen, during insertion or removal. In particular, the malleable element can eliminate the need for a separate guidewire or stylet for inserting the catheter, simplifying surgical procedures. However, the malleable element should not be excessively rigid, to avoid damaging fragile tissues. The malleable element further can permit a shape to be temporarily or permanently imparted to the catheter. Thus, the catheter can be easily and accurately placed in the patient's body. For example, the malleable element can be conformed to a shape of a body lumen, or can be formed to permit the balloon to be placed at a body site not readily accessible by conventional means. Also, the malleable element can provide a means for securing or anchoring the implantable device in a patient's body and preventing the catheter from "backing out" during or after surgical placement.

The malleable element can comprise, a flexible wire, which can be embedded in a wall of the catheter, secured to an inner or outer surface of a sidewall of the catheter, or can be situated in the lumen of the catheter. Thus, for example, FIG. **2**A depicts a cross-sectional view of one embodiment of a catheter along line **2**—**2** of FIG. **1**. The sidewall **34** of the catheter **26** defines a catheter lumen **36**. A malleable wire **28** is embedded in the sidewall **34**. FIG. **2**B depicts a catheter in which a malleable element **28** is secured to the sidewall **34** in the catheter lumen **36** of catheter **26**. The wire can be made of, stainless steel, titanium and other metals, and alloys thereof. A preferred malleable element is a titanium wire, e.g., a 20 mil annealed titanium wire. In one embodiment, the malleable element comprises a metallic element or alloy, such as nitinol, which exhibits "shape memory," i.e., has the property of returning to a predefined shape upon heating. In this embodiment, the wire can be selected to have a desired shape when implanted, but can be bent to a different shape prior to insertion to accommodate placement in vivo, and then heated (e.g., with a resistive heater) to restore the preselected shape. In certain preferred embodiments, the malleable element comprises a metallic element or alloy which does not substantially interfere with NMR measurements, e.g., magnetic resonance imaging; i.e., NMR measurements of the patient's body can be performed while the malleable element is present in the patient's body. In this embodiment, non-ferromagnetic metals or alloys are preferred. A preferred malleable element comprises an annealed titanium wire, preferably about 20 mil in diameter.

Such a wire can also be employed to provide a source of electric current, e.g., to a resistive heater, or to provide means for monitoring conditions, e.g., temperature, inside the patient's body. Thus, a malleable wire can provide means for additional treatment modalities, e.g., heat therapy, which can be employed in conjunction with chemotherapy and brachytherapy, if desired. Additionally, the malleable element can be employed as a radio-opaque marker for locating the catheter in the body.

The inflatable treatment devices include an inflatable balloon for containing a treatment fluid in close proximity to the tissue to be treated. It will be understood that the term "balloon" is intended to include distensible devices which can be, but need not be, constructed of an elastic material. A variety of balloons or other distensible devices for use with surgical catheters are known in the art and are contemplated for use in the invention; many balloons are commercially available. In one embodiment, the balloon is constructed of a material that is substantially impermeable to the active components of the treatment fluid with which it is filled, and is also impermeable to body fluids, e.g., blood, cerebrospinal fluid, and the like. An impermeable balloon is useful in conjunction with a radioactive treatment fluid, to prevent the radioactive material from escaping the treatment device and contaminating the surgical field or tissues of the patient. In another embodiment, the balloon is permeable to the treatment fluid, and permits the fluid to pass out of the treatment device and into a body lumen or cavity. A permeable balloon is useful when the treatment fluid is a chemotherapeutic agent which must contact tissue to be effective. Semi-permeable balloons can also find use in the inventive devices. For example, a semipermeable material that is capable of preventing the passage of a radioactive material through the balloon wall can be used to contain a radioactive treatment fluid, where certain fluid components can pass through the membrane while the radioactive component is retained within the balloon. In some embodiments, isotonic fluids are preferred for use in semipermeable balloons, as discussed below. Silicone, e.g., NuSil, is a preferred material for a balloon wall.

In general, it is preferable that the balloon have a shape that permits the balloon to conform to the body cavity or lumen in which the balloon is to be inflated. For example, a generally spherical cavity can be filled with a substantially spherical balloon, while an elongated balloon shape is suitable for an elongated body lumen such as a blood vessel. Irregular balloon shapes may also find application in the subject devices and methods. In certain embodiments, a balloon will be selected such that, upon inflation, the balloon does not compress the tissue which is being treated, or surrounding tissues. Thus, when a radioactive treatment fluid is introduced into the device, e.g., by injection, the inflatable treatment device is inflated to a volume not substantially greater than a volume of the body cavity in which the device has been placed, thereby avoiding any substantial compression or distortion of normal tissue. For example, in one embodiment, when the balloon is placed within a cavity left by surgical removal of tissue, the balloon is not inflated to a size substantially larger than the size of the cavity. However, in certain embodiments, the balloon preferably is inflated to compress tissue. For example, when the proliferative disorder being treated is, e.g., restenosis of a blood vessel, the balloon can be inflated to a size large enough to compress the excess tissue, while also providing chemotherapy, brachytherapy, or the like to treat the lesion. Thus, a balloon can be selected to have a desired size, and the amount of treatment fluid can be adjusted to attain an inflation of the balloon to achieve the desired size. In general, the balloon should have a small profile, e.g., a small size, when deflated, to permit facile placement in the patient's body and to minimize the size of a surgical incision needed to place the balloon at the desired site of action.

In some embodiments, a balloon is attached to the catheter at substantially a single point on, or a single side of, the balloon body. Catheters suitable for use in the invention are well known in the art. A preferred catheter material is radio-opaque silicone. Attachment of a balloon to a catheter at a single point on the balloon body permits the balloon (e.g., a spherical balloon) to maintain a substantially constant (e.g., spherical) shape over a range of inflation volumes. That is, the balloon is not constrained in shape by multiple attachment points to the catheter, as is commonly the case with, e.g., balloons for Foley catheters. In other embodiments, the balloon is attached to the catheter at multiple points on the balloon body, while allowing the balloon to maintain a constant shape over a range of inflation sizes. For example, a balloon attached to a catheter at both distal and proximal points on the balloon body can be unconstrained upon inflation where the catheter includes an expansion element (e.g., a slidable engagement element) that permits the catheter to adjust in length as the balloon expands or contracts. A balloon which maintains a substantially constant shape over a range of inflation volumes permits a surgeon to select a balloon to conform to a cavity of a particular shape with less concern over the size of the cavity. Thus, devices that include such a balloon reduce the need for the surgeon to prepare several different-sized balloons prior to surgery.

The invention also contemplates the use of multiple balloons, e.g., a double-walled balloon. Such a balloon can comprise, for example, an impermeable inner wall and a permeable outer wall. In this embodiment, the inner balloon can be filled with, e.g., a radioactive treatment fluid, while the outer balloon (i.e., the space between the inner and outer balloon walls) is filled with a chemotherapeutic treatment fluid. This embodiment allows two modes of therapy (e.g., chemotherapy and brachytherapy) to be administered simultaneously with a single device. In this double-walled balloon embodiment, the device preferably includes two treatment fluid receptacles, one in communication with each of the two balloons, preferably through a separate catheter, one catheter fluidly connected to each balloon and treatment fluid receptacle. The two balloons can thus be inflated with two treatment fluids at the same time or at different times during therapy. Inflation of an inner balloon can provide pressure on an outer balloon, which can cause the outer balloon to expand, or can force or urge fluid in the space between the inner and outer balloon walls through the membrane of a porous outer balloon. Higher-order balloons, e.g., triple-walled balloons, can also be used in the inventive devices.

Thus, for example, FIG. **3** shows a double-balloon device of the invention. The device has two treatment fluid receptacles **20**, **21**, each having an elastomeric seal **22** secured thereto. Receptacle **20** is fluidly connected to outer balloon **24** through catheter **26**, which includes a malleable element **28**, and receptacle **21** is fluidly connected to inner balloon **40** by catheter **27**, which includes diffusion barrier **32**. The device of FIG. **3** is useful where a chemotherapeutic fluid **30** is used to inflate the outer balloon **24**, while a radioactive fluid **42** fills the inner balloon **40**. Diffusion barrier **32** prevents flow of the radioactive fluid **42** from the balloon **40** to the catheter **27**.

The catheter element can be any of a variety of catheters known in the art. A preferred catheter material is silicone,

preferably a silicone that is at least partially radio-opaque, thus facilitating x-ray location of the catheter after implantation of the device. The catheter can also include conventional adapters for attachment to the treatment fluid receptacle and the balloon, as well as devices, e.g., right-angle devices, for conforming the catheter to contours of the patient's body.

In some embodiments, the inventive devices are provided in pre-assembled form, i.e., the components are assembled in advance of a surgical insertion procedure. In certain embodiments, however, the inventive devices are configured to permit modular assembly of components, e.g., by a surgeon. Thus, for example, a treatment fluid receptacle can be provided with an element adapted for connection to any one of a plurality of catheters. The connection element can be, e.g., any element known in the art for effecting connection between components such as catheters, injection ports, and the like. Illustrative connectors include luer adapters and the like. In this embodiment, a variety of catheters and balloons can be provided, each of which is adapted for facile connection to the treatment fluid receptacle. The surgeon can then select an appropriate size and shape of balloon for treatment of a particular proliferative disorder without need for providing several treatment fluid receptacles. The catheter and balloon can be selected according to the results of pre-operative tests (e.g., x-ray, MRI, and the like), or the selection can be made based on observation, during a surgical procedure, of the target cavity (e.g., a surgical cavity resulting from tumor excision). When the surgeon selects an appropriate balloon (e.g., a balloon having a size and shape suitable for placement in a body cavity), the catheter and balloon can then be attached to the pre-selected treatment fluid receptacle, thereby assembling the treatment device.

The above-described implantable inflatable treatment devices can be employed in the treatment of proliferative disorders in a patient. In one aspect, the invention provides a method of treating proliferative disorders including the step of implanting in the patient's body an inflatable treatment apparatus, in which the apparatus includes a small-volume treatment fluid receptacle for receiving a treatment fluid; an inflatable balloon having a balloon body; a catheter connected between the treatment fluid receptacle and the balloon and defining a fluid flow path therebetween; and a diffusion barrier disposed in the fluid flow path between the treatment fluid receptacle and the balloon; wherein the balloon is secured to the catheter such that the balloon maintains a substantially constant shape during inflation; and introducing a treatment fluid into the treatment fluid receptacle so that the balloon is inflated, such that the proliferative disorder is treated. In certain embodiments, the method includes the step of selecting a balloon for treatment a proliferative disorder in a patient. In some embodiments, the method includes, prior to the implanting step, the further step of assembling an inflatable treatment apparatus.

The treatment devices of the invention (or any part thereof, e.g., the balloon) can be implanted according to surgical methods well known to the skilled artisan. In one embodiment, the balloon is implanted in a cavity formed by removal of tissue from a tumor or organ. Thus, in certain embodiments, the method includes the step of surgically removing tissue to form a cavity in the patient's body prior to implanting the inflatable device. In other embodiments, the device is implanted in a natural body cavity, e.g., in the abdominal cavity, or an organ such as a lung, uterus, or prostate gland. In yet other embodiments, a cavity or space, for placement of the inventive device in a patient's body, can be formed by displacing, compressing, or otherwise repositioning tissue, without surgically removing tissue. Illustratively, tissue can be compressed, e.g., by inflation of a balloon, prior to placement of a device of the invention in the cavity formed thereby. In certain embodiments, the treatment fluid receptacle is implanted subcutaneously. It will be appreciated that the catheter or catheters of the device can be implanted so as to pass through a body wall, e.g., the skull, the abdominal wall, and the like.

The treatment fluid (or fluids) for inflating the balloon (or balloons) can be provided to the treatment fluid receptacle by, e.g., transcutaneous injection into an injection port(s). Injection can be with a syringe, e.g., a hypodermic syringe, or with a pump or other mechanical delivery means.

In certain preferred embodiments, the proliferative disorder is a tumor, more preferably a solid tumor, including both benign and malignant tumors. In some embodiments, the tumor is a cancerous tumor. Methods of the invention are useful in treating cancers such as, without limitation, brain tumors, breast tumors, prostate tumors, ovarian tumors, and the like. In another preferred embodiment, the proliferative disorder is restenosis, e.g., of a blood vessel. Thus, the subject method can be employed to treat or to prevent restenosis in a patient. Similarly, the subject method can be employed to treat hyperplasia, including endometriosis, benign prostatic hyperplasia, and the like.

In certain embodiments, the treatment fluid includes a chemotherapy agent. Formulation and dosage of chemotherapy agents is routine to the skilled artisan. In certain embodiments, the treatment fluid includes a radioisotope. Radioactive treatment fluids are useful for brachytherapy, as discussed supra. Preferred radioisotopes for brachytherapy include ^{90}Y, ^{198}Au, ^{32}P, ^{125}I, and ^{131}I. Radioisotope preparations suitable for use in the subject treatment devices are known to those of skill in the art. It will be appreciated that a treatment fluid can be formulated to provide more than one treatment modality. For example, a chemotherapy fluid can be heated to provide both chemotherapy and heat therapy. In certain embodiments, the treatment fluid is approximately isotonic with body fluids; that is, the tonicity (ionic strength) of the treatment fluid is close to that of physiological fluids. Use of isotonic treatment fluids avoids transfer of solutions across the balloon body membrane, thereby preventing unexpected or undesired inflation or deflation of the balloon, or dilution or concentration of the treatment fluid.

In certain embodiments, the method of treatment includes the further step of flushing the treatment fluid receptacle (e.g., the injection port) with a flush fluid. As previously described, it is important to avoid damaging healthy tissue by exposure to high doses of radiation from the treatment fluid. Thus, to prevent damage to tissue adjacent the injection port and the catheter, the injection port and catheter can be flushed with a non-radioactive flush fluid. In certain embodiments, the flush fluid is flushed into the balloon. In this embodiment, the volume of flush fluid should be carefully regulated to ensure that the balloon does not become overinflated. In certain embodiments, the flush fluid inflates the balloon by no more than 20%, more preferably no more than 10%. Alternatively, the flush fluid can be withdrawn from the treatment device, e.g., by removal with a needle introduced into the injection port. In this embodiment, the balloon is preferably not significantly further inflated, e.g., inflation due to the flush solution is less than 10%, more preferably less than 5%, of the volume of the inflated balloon. In some preferred embodiments, e.g., where a radioactive treatment fluid has been employed, the flushing step can reduce the level of radioactivity present in the

treatment fluid receptacle or the catheter by at least about 50%, more preferably by at least 80%, and still more preferably by at least 90%.

In certain embodiments, the flush solution has approximately physiological tonicity. In some embodiments, the flush solution is more viscous than the treatment fluid such that the flow of the flush fluid approaches plug flow. A viscous flush solution can also prevent backflow or diffusion of a radioactive treatment fluid because the higher viscosity impedes flow in the catheter lumen.

The treatment is preferably continued until the proliferative disorder has been significantly ameliorated, e.g., if the proliferative disorder is a tumor, treatment is continued until the tumor has decreased in size by at least about 10%, more preferably at least about 20%. The inflatable device can be left in place and repeated filled with treatment fluid, if desired. For example, repeated doses of a chemotherapy fluid can be administered without disturbing the placement of the device, simply by injecting more treatment fluid into a permeable balloon after-the original dose has passed through he balloon. Similarly, a radioactive fluid can be removed, e.g., to prevent excessive doses of radiation or when the radioisotope has decayed, and replenished by addition of fresh radioisotope solution. Where it is desired to use repeated doses, the strength of the doses can be varied, for example, a first, strong dose, followed by a second, less potent dose. Determination of appropriate dosages strengths and treatment regimens will be routine for the skilled artisan.

The contents of each patent, patent application, and publication cited herein are hereby incorporated by reference.

Those skilled in the art will recognize, or be able to ascertain using no more than routine experimentation, numerous equivalents to the methods and devices described herein. Such equivalents are considered to be within the scope of this invention and are covered by the following claims.

What is claimed is:

1. An implantable apparatus for treating a proliferative disorder in a patient, comprising:

a treatment fluid receptacle for receiving a treatment fluid;

an inflatable balloon having a balloon body;

a catheter connected between the treatment fluid receptacle and the balloon and defining a fluid flow path therebetween; and

a diffusion barrier disposed in the fluid flow path between the treatment fluid receptacle and the balloon.

2. The apparatus of claim **1**, wherein the treatment fluid receptacle has a small volume and is adapted to be implanted subcutaneously in the body of the patient.

3. The apparatus of claim **1**, wherein the diffusion barrier is a narrow flow segment.

4. The apparatus of claim **1**, wherein the balloon has a substantially spherical shape when inflated.

5. The apparatus of claim **1**, wherein the balloon is secured to the catheter at substantially a single point on the balloon body.

6. The apparatus of claim **1**, wherein the balloon is secured to the catheter at a plurality of points on the balloon body.

7. The apparatus of claim **1**, wherein the catheter further comprises a malleable element.

8. The apparatus of claim **1**, wherein the balloon body is substantially impermeable to the treatment fluid.

9. The apparatus of claim **1**, wherein the balloon comprises a semipermeable membrane.

10. The apparatus of claim **1**, wherein the treatment fluid receptacle is sized and dimensioned for being flushed with a flushing fluid without substantially expanding the balloon.

11. The apparatus of claim **1**, wherein the balloon is secured to the catheter such that the balloon maintains a pre-selected shape during inflation.

12. The apparatus of claim **1**, wherein the balloon comprises a double-walled balloon having an inner wall and an outer wall.

13. The apparatus of claim **1**, wherein the balloon is sized and dimensioned for placement in a blood vessel.

14. The apparatus of claim **1**, wherein the balloon is sized and dimensioned for placement in a cavity left by surgical removal of a tumor from the patient.

15. The apparatus of claim **1**, wherein the balloon is sized and dimensioned for placement in a natural body cavity.

16. The apparatus of claim **1**, wherein the balloon is filled with a treatment fluid.

17. The apparatus of claim **16**, wherein the treatment fluid is a radioactive fluid.

18. The apparatus of claim **16**, wherein the treatment fluid has substantially physiological tonicity.

19. The apparatus of claim **12**, further comprising a second treatment fluid receptacle.

20. The apparatus of claim **19**, wherein the second treatment fluid receptacle fluidly communicates with a volume between inner and outer balloon walls.

21. An implantable apparatus for treating a proliferative disorder in a patient, comprising:

a treatment fluid receptacle for receiving a treatment fluid;

an inflatable balloon having a balloon body; and

a catheter connected between the treatment fluid receptacle and the balloon and defining a fluid flow path therebetween;

wherein the catheter further comprises a malleable element.

22. The apparatus of claim **21**, wherein the malleable element does not substantially interfere with NMR analysis.

23. The apparatus of claim **21**, wherein the balloon is sized and dimensioned for placement in a blood vessel.

24. An implantable apparatus for treating a proliferative disorder in a patient, comprising:

a treatment fluid receptacle for receiving a treatment fluid;

an inflatable balloon having a balloon body;

a catheter connected between the treatment fluid receptacle and the balloon and defining a fluid flow path therebetween; and

a diffusion barrier disposed in the fluid flow path between the treatment fluid receptacle and the balloon;

wherein the treatment fluid receptacle is adapted to be flushed with a small volume of a flush fluid.

25. A method for treating a proliferative disorder in a patient, the method comprising the steps of:

implanting in the patient's body an inflatable treatment apparatus, the apparatus comprising:

a treatment fluid receptacle for receiving a treatment fluid;

an inflatable balloon having a balloon body;

a catheter connected between the treatment fluid receptacle and the balloon and defining a fluid flow path therebetween; and

a diffusion barrier disposed in the fluid flow path between the treatment fluid receptacle and the balloon; and

introducing a treatment fluid into the treatment fluid receptacle such that the balloon is inflated;

such that the proliferative disorder is treated.

26. The method of claim **25**, further comprising the step of flushing the treatment fluid into the balloon.

27. The method of claim **25**, wherein the treatment fluid is flushed into the balloon with a flush fluid.

28. The method of claim **27** wherein the flush fluid further inflates the balloon by no more than 10% of the balloon volume prior to the flushing step.

29. The method of claim **25**, wherein the implanting step comprises the step of positioning the inflatable balloon adjacent to a tumor.

30. The method of claim **29**, wherein the implanting step comprises the step of positioning the inflatable balloon adjacent to a solid tumor.

31. The method of claim **29**, wherein the implanting step comprises the step of positioning the inflatable balloon adjacent to a cancerous tumor.

32. The method of claim **29**, wherein the implanting step comprises the step of positioning the inflatable balloon adjacent to a brain tumor.

33. The method of claim **29**, wherein the implanting step comprises the step of positioning the inflatable balloon adjacent to a breast tumor.

34. The method of claim **25**, further comprising, prior to the implanting step, the step of surgically creating a cavity in the patient's body.

35. The method of claim **25**, further comprising, prior to the implanting step, the step of selecting a balloon for treating the proliferative disorder.

36. The method of claim **35**, further comprising, prior to the implanting step, the step of assembling the inflatable treatment apparatus.

37. The method of claim **25**, wherein the apparatus is implanted in a natural body cavity.

38. A method for treating a proliferative disorder in a patient, the method comprising:

determining a characteristic of a cavity in the patient's body, the characteristic being selected from the group consisting of volume, shape, or a dimension;

selecting an inflatable balloon suitable for placement in the cavity, the balloon including a balloon body;

implanting in the cavity an inflatable treatment apparatus comprising:

a treatment fluid receptacle for receiving a treatment fluid;

the inflatable balloon;

a catheter connected between the treatment fluid receptacle and the balloon and defining a fluid flow path therebetween;

a diffusion barrier disposed in the fluid flow path between the treatment fluid receptacle and the balloon; and

introducing a treatment fluid into the treatment fluid receptacle such that the balloon is inflated;

such that the proliferative disorder is treated.

39. The method of claim **38**, wherein the treatment fluid is a radioactive fluid.

40. The method of claim **38**, wherein the treatment fluid is a chemotherapy fluid.

41. The method of claim **38**, the method comprising, prior to the implanting step, the further step of assembling the inflatable treatment apparatus.

42. An implantable apparatus for treating a proliferative disorder in a patient, said apparatus comprising:

a treatment fluid receptacle for receiving a treatment fluid;

an inflatable balloon having a balloon body;

a catheter connected between said treatment fluid receptacle and said balloon, said catheter defining a fluid flow path therebetween; and

a narrow flow segment disposed in said fluid flow path between said treatment fluid receptacle and said balloon.

43. An implantable apparatus for treating a proliferative disorder in a patient, said apparatus comprising:

a treatment fluid receptacle for receiving a treatment fluid;

an inflatable balloon having a balloon body;

a catheter connected between said treatment fluid receptacle and said balloon, said catheter defining a fluid flow path therebetween;

a malleable element coupled to said catheter, and

a diffusion barrier disposed in the fluid flow path between said treatment fluid receptacle and said balloon.

* * * * *

Exhibit VV

CANACCORD Adams

Flash Update | 1

19 February 2008

SenoRx

SENO : NASDAQ : US$8.61

BUY

Target: US$12.25

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jamar.ismail@canaccordadams.com

COMPANY STATISTICS:

52-week Range:	US$7.1 - 11.10
Market Cap (M):	US$147.7
Shares Out (M):	17.1

SHARE PRICE PERFORMANCE:

COMPANY SUMMARY:

SenoRx designs, manufactures and markets minimally invasive medical devices used primarily in the diagnosis and treatment of breast cancer. Its core competency is percutaneous biopsy procedures, and its EnCor vacuum-assisted device for this market has many "pre-programmed" features, the TriCor concave tip, and a unique collection chamber. EnCor can be used with stereotactical (x-ray), ultrasound, and MRI imaging modalities.

All amounts in US$ unless otherwise noted.

Life Sciences -- Biomedical Devices and Services

QUICK TAKE – STRONG Q4 REVENUE GROWTH CAPS OFF SOLID YEAR – MAINTAIN BUY RATING

Event

SenoRx reported Q4 results.

Action

We maintain our BUY rating.

Key points

Q4 revenue of $10.3M (+43% Y/Y) modestly beat our $10.2M estimate, led by strong biopsy disposable sales, which increased 43% versus our 42% growth expectation. Notably the company's revenue result for the year of $35.0M was at the high end of the $33-35M guidance that was originally given early in the year, post the march IPO. Hitting the top line is a notable achievement for a recently minted IPO company and gives us confidence that SenoRx can repeat that performance in 2008, especially with all the new product launches. We think top-line performance is the most important metric on which investors should focus at this point in the company's life cycle.

- SenoRx reiterated 2008 revenue guidance of $46-50M, which compares to our current estimate of $49.5M.
- SenoRx had penetrated 34 centers with its breast brachytherapy balloon Contura exiting 2007 versus our 20-center estimate; however, revenue associated with this penetration came in at about $300K versus our $900K estimate. Our checks have suggested in recent weeks that the company is supplying the early adopting centers – many of which are academic teaching institutions – with product at a lower price than what we think is the commercialized price (~$2,500-2,600).

Gross margin increased over 1,250bps Y/Y to 56% from 43.5%, albeit it was modestly lower than our 57.7% estimate as capital equipment revenue ($1.2M) doubled our estimate ($0.6M). Biopsy equipment revenues carry much lower GM than disposables and markers, while Contura balloon placements' below-market ASPs likely contributed as well.

Operating expenses totaling $8.7M significantly exceeded our $7.1M estimate as the company invested heavily in pre-launch sales and marketing resources ahead of full launch of Contura, VisiLoc and SenoSonix, all of which we expect to contribute meaningfully to growth in 2008.

- We are not at all concerned about the higher OpEx spending in the quarter; to wit, we think a company such as SenoRx in the earlier stages of a rapid growth trajectory should "strike while the iron is hot" in order to take advantage of growth opportunities in its key markets – namely breast cancer diagnosis and treatment.
- What's more, the company exited the quarter with $28M in cash, an untapped $4M credit facility and now virtually no long-term debt, owing to the retirement of a high-interest-rate loan facility in the quarter (11.5% interest rate) that consumed $10.3M in cash. In sum, we think the company is on solid financial footing.

Given the higher OpEx, partially offset by modestly higher revenue than we expected, the company reported GAAP net loss of $(0.23) per share versus our estimate of $(0.12)/share net loss.

We look forward to continued strong revenue growth and shrinking net loss for SenoRx in 2008. At this point we do not expect major changes to our current 2008 revenue and EPS estimates of $49.5M (+41.3%) and $(0.13), respectively.

We reiterate our BUY rating. Our price target is currently $12.25/share based on 4.0x EV/2008E sales of $49.5M. We will have more after the company's conference call, which will be conducted later today.

Investment risks

Financial and distribution strength of VAB biopsy competitors, uncertainty over which technology will "win" in breast brachytherapy, increased use of MRI and ultrasound, reimbursement and potential for pricing erosion.

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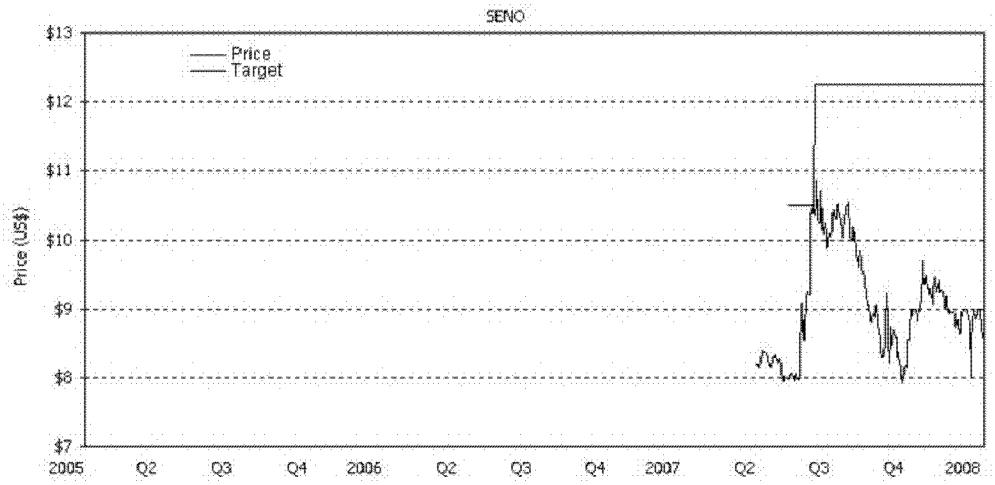
Site Visit: An analyst has visited the issuer's material operations in Aliso Viejo, California. No payment or reimbursement was received from the issuer for the related travel costs.

Price Chart:*



	Date	Analyst	Rating	Target Price
1)	05/08/07	JM	Buy	10.50
2)	06/07/07	JM	Buy	12.25

* Price charts assume event 1 indicates initiation of coverage or the beginning of the measurement period.

Distribution of Ratings:
Global Stock Ratings
(as of 1 February 2008)

	Coverage Universe		IB Clients
Rating	#	%	%
Buy	313	60.3%	43.1%
Speculative Buy	62	11.9%	71.0%
Hold	128	24.7%	24.2%
Sell	16	3.1%	6.3%
	519	100.0%	

Canaccord Ratings System:

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HOLD: The stock is expected to generate risk-adjusted returns of 0-10% during the next 12 months.
SELL: The stock is expected to generate negative risk-adjusted returns during the next 12 months.
NOT RATED: Canaccord Adams does not provide research coverage of the relevant issuer.

"Risk-adjusted return" refers to the expected return in relation to the amount of risk associated with the designated investment or the relevant issuer.

Risk Qualifier: **SPECULATIVE**: Stocks bear significantly higher risk that typically cannot be valued by normal fundamental criteria. Investments in the stock may result in material loss.

Canaccord Adams Research Disclosures as of 19 February 2008

Company	Disclosure
SenoRx	1A, 2, 3, 5, 7

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Exhibit WW

CANACCORD Adams

Daily Letter | 1

20 February 2008

SenoRx

SENO : NASDAQ : US$8.64

BUY

Target: US$12.25

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Jamar Ismail, CPA 1.415.229.0683
jamar.ismail@canaccordadams.com

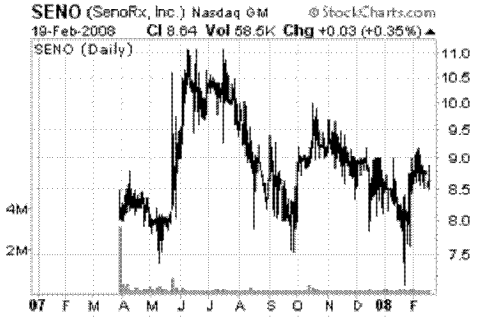
COMPANY STATISTICS:

52-week Range:	US$7.10 - 11.10
Market Cap (M):	US$147.7
Shares Out (M):	17.1

EARNINGS SUMMARY:

FYE Dec		2007A	2008E	2009E
Revenue (M):		35.0	49.5	67.2
EPS:		(0.59)	(0.28)	0.23
Revenue (M):	Q1	7.7	10.7	-
	Q2	8.1	11.7	-
	Q3	8.9	12.5	-
	Q4	10.3	14.6	-
Total		35.0	49.5	67.2
EPS:	Q1	(0.20)	(0.12)	-
	Q2	(0.15)	(0.09)	-
	Q3	(0.10)	(0.06)	-
	Q4	(0.16)	(0.01)	-
Total		(0.59)	(0.28)	0.23

SHARE PRICE PERFORMANCE:



COMPANY SUMMARY:

SenoRx designs, manufactures and markets minimally invasive medical devices used primarily in the diagnosis and treatment of breast cancer. Its core competency is percutaneous biopsy procedures, and its EnCor vacuum-assisted device for this market has many "pre-programmed" features, the TriCor concave tip, and a unique collection chamber. EnCor can be used with stereotactical (x-ray), ultrasound, and MRI imaging modalities.

All amounts in US$ unless otherwise noted.

Life Sciences -- Biomedical Devices and Services

SOLID Q4 – MAINTAIN BUY RATING

Event

SenoRx reported Q4 results highlighted by strong revenue growth.

Action

We maintain our BUY rating and $12.25 price target

Key points

Q4 revenue of $10.3M (+43% Y/Y) modestly beat our/consensus $10.2M estimate. Notably 2007 revenue of $35.0M hit the high end of $33-35M guidance originally given after its March IPO. Pro-forma EPS of $(0.16) compared to our $(0.05) estimate, driven by higher spending to support product launches and add sales reps – a strategy we believe is best to sustain strong growth. **Gross margin increased over 1,250bps Y/Y to 56.0% from 43.5%, albeit modestly lower than our Q4 estimate.**

Revenue growth was led by strong biopsy disposable sales, which increased 43% versus our 42% growth expectation, and system revenue of $1.1M doubled our estimate. Adjunct sales (Markers & Gamma detection) were $4.1M and Contura sales were $0.3M.

Encore placements in Q4 were very strong at 80 units and represent a strong leading indicator of future disposable sales. Importantly, SEMP estimated its current VAB disposables market share is 15%, while current share of new system placements eclipses 35%. We view this disparity as a favorable signal that biopsy disposable growth can continue to grow robustly – perhaps higher than our 2008 estimates.

SenoRx reiterated 2008 revenue guidance of $46-50M. We maintain our $49.5M estimate (+41% Y/Y), albeit we widen our net loss/share estimate to $(0.28) from $(0.12) as we expect SenoRx to "strike while the iron is hot" to further develop core growth markets and continue to gain share.

We reiterate our BUY rating and $12.25 target (4x our 2008E sales).

Bottom line – We suggest SenoRx possesses scarcity value within a consolidating breast device space that we think could justify a premium valuation. Reflecting conservatism, however, our $12.25 target reflects an EV/Sales multiple of 4.0x, which is a 22% discount to the small-cap med-tech comparable group multiple of 5.1x. We apply this 4.0x multiple to our 2008 sales estimate of $49.5 million to derive our 12-month price target.

DISCUSSION

SenoRx reported Q4/07 revenue of $10.3M (+43% Y/Y) modestly beating our and consensus estimates of $10.2M. Operating loss was $2.9M and pro-forma net loss per share was $(0.16), compared to an operating loss of $3.2M in Q4/06. This was below our estimate for operating loss of $1.2M and net loss per share of $(0.05) and below consensus net loss per share of $(0.10). GAAP net loss per share of $(0.23) includes $1.1M of expenses related to the early extinguishment of debt.

Notably the company's revenue result for the year of $35.0M was at the high end of the $33-35M guidance that was originally given early in the year post the March IPO. We think this top-line result relative to guidance and consensus is a notable achievement for a recently minted IPO company and gives us confidence that the company can repeat this strong performance in 2008, especially given several new product launches – Contura MLB, VisiLoc and SenoSonix system. We continue to recommend investors focus on the top-line performance, which we think is the most important metric to watch at this early point in the company's life cycle.

Revenue by segment:

- **Revenue growth was led by strong biopsy disposable sales of $4.7M** (+43% Y/Y) slightly better than our expectation of $4.6M (+42% Y/Y).
- **Placements were very strong. Equipment revenue was $1.1M (+Y/Y), vs. our expectation of $0.6M.** Total EnCor system placements were 80 units, up from 50 in Q3/07, 45 in Q4/06 and higher than our estimate of 51. Cumulative systems reached 536 at the end of 2007, up from 317 at the end of 2006. Given that laser placements represent a leading indicator of the ultra-important disposable EnCor biopsy sales in this prototypical razor/razor-blade model, we submit that the stronger system placements in Q4 – and previously in Q3 as well – give us increasing confidence in strong 2008 disposables sales. Importantly, management estimates that its current market share of disposables is 15%, while current share of new system placements is greater than 35%, owing to momentum over the past year. We think this represents a positive signal for SenoRx, and suggests to us that biopsy disposable growth should continue to exhibit strong growth in 2008 – perhaps higher than our current model, which calls for biopsy disposables sales growth of 39.1% Y/Y.
- **Diagnostic adjunct sales** (Markers & Gamma detection) were $4.1M (+ Y/Y), matching our estimate.
- **Contura sales** were $329K vs. our estimate of $900K. SenoRx had penetrated 34 centers with its breast brachytherapy balloon Contura exiting 2007 versus our 20-center estimate; however, revenue associated with this penetration came in lower than expected. Our checks have suggested in recent weeks that the company is supplying the early adopting centers – many of which are academic teaching institutions – with product at no charge. Additionally, in the early stages of this launch the company in

some instances had to swap out existing inventory of competitor product and/or pay re-stocking fees up to 20%, both of which counted against average ASPs for Contura in the quarter. We think these "offsets" will decline throughout 2008, and continue to see the company achieving an average ASP – all things being equal – in the $2500-2700 range in H2/2008 and 2009.

Gross margin increased over 1,250bps Y/Y to 56.0% from 43.5%, albeit were modestly lower than our 57.7% estimate, owing to 1) lower-margin capital equipment revenue doubling our estimate (about 1/3 of the shortfall, according to management), 2) higher international sales which are also lower margin relative to domestic sales, and 3) re-valuation of inventory via the shift of the rest of its manufacturing overseas to Thailand, including increasing its obsolescence reserve because of discontinuation of Anchor Guide (this resulted in 1.5% of the shortfall and WILL NOT recur).

We see significant gross margin expansion going forward, with our model for GM increasing sequentially in 2008 and reaching 64.4% exiting the year. We model GM of 61.8% for the full year 2008 and 66% in 2009 driven by increased disposable sales and additional manufacturing efficiencies.

Operating expenses totaling $8.7M significantly exceeded our $7.1M estimate as the company invested heavily in pre-launch sales and marketing resources ahead of full launch of Contura, VisiLoc and SenoSonix, all of which we expect to contribute meaningfully to growth in 2008.

- We are not at all concerned about the higher OpEx spending in the quarter; to wit, we think a company such as SenoRx in the earlier stages of a rapid growth trajectory should "strike while the iron is hot" in order to take advantage of growth opportunities in its key markets – namely breast cancer diagnosis and treatment.
- What's more, the company exited the quarter with $28M in cash; an untapped $4M credit facility and now virtually no long-term debt, owing to the retirement of a high interest rate loan facility in the quarter (11.5% interest rate) that consumed $10.3M in cash. In sum, we think the company is on solid financial footing.

Given the higher OpEx, partially offset by modestly higher revenue than we expected, the company reported pro-forma loss per share of $(0.16) vs. our estimate of $(0.05). GAAP net loss per share was $0.23 v. our estimate of $0.12/share net loss.

SenoRx reiterated 2008 revenue guidance of $46-50M, which compares to our current estimate of $49.5M and consensus of $49.9M.

Estimate changes. For 2008 we are keeping our revenue estimate at $49.5M (+41.4%) and widening our loss per share estimate to $(0.28) from $(0.12) to account for increased product launch expenses and $1.4-$1.7M in incremental legal expenses associated with litigation to defend itself against a lawsuit recently brought by Hologic regarding Contura. For 2009 we are maintaining our estimates of revenue of $67.2M and EPS of $0.23. We think the company can turn EBITDA positive in Q4/08 or Q1/09.

Product initiative update

Contura – The company initiated full US commercial launch in January. Q4/07 revenue was lower than expected but as we mentioned earlier our checks suggest that the company has been offering product to teaching medical centers at a discount. The company expects some of these centers to begin publishing abstracts soon. Positive data – especially data that suggests the multi-lumen aspect of Contura will allow more patients to be treated – are key to adoption and market expansion. We have tempered our revenue expectation for 2008 and now see a $6M contribution from Contura for the year versus our previous estimate of $7.5M, as we expect continued impact in H1/2008 from the teaching hospital placements, re-stocking fees and inventory swap charges noted earlier.

VisiLoc – This extension to the EnCor system was FDA 510k approved in November 2007. The VisiLoc MRI Visible Obturator allows for more precise location of the target tumor in MRI assisted breast biopsy. We think VisiLoc could be an important differentiator of the Encor platform, and could help SenoRx grab even more share of the vacuum assisted biopsy market, especially if/as procedures move toward MRI relative to stereotactic guidance.

SenoSonix – This combination biopsy/ultrasound device was FDA 510K approved in October 2007 and the company has initiated a launch in the US office segment. We do not model significant revenue from this segment. European launch will be more significant, in our view, as European physicians perform a higher percentage of ultrasound guided biopsies. The company expects to receive CE Mark this quarter.

Training and Sales Force. The company continues to spend on educational seminars and conducted a total of 64 in 2007 during which ~1,355 doctors were trained on SenoRx products. This initiative will continue in 2008 and will include seminars focused on Contura. In addition the company continued to add to its US and international sales infrastructure – including 5 brachytherapy specialists – which we also expect to continue to grow in 2008 and 2009.

- **Sales force expansion is important to growth, in our view.** SenoRx significantly expanded its direct US sales force in 2006 on the heels of the EnCor biopsy system launch in late 2005, and this expansion continued in 2007, including the addition of a five brachytherapy sales specialist group, whose expertise should be valuable in marketing SenoRx's proprietary Radiation Balloon to surgeons and radiation-oncologists. In total, SenoRx exited 2007 with a direct sales organization totaling 65, including 47 quota-carrying reps and nearly 20 clinical specialists. We expect the sales force additions to continue in 2008. The company is also taking steps to expand and bolster its OUS direct and distributor sales force

Investment thesis

We are maintaining our Buy rating and $12.25 price target. We think that this was a solid quarter to end a solid year for SenoRx. Positives include continued strong biopsy disposable sales growth of 42% as the company gains market share, impressive and accelerating EnCor system placements which bode well for future disposable growth and gross margin expansion Y/Y that we expect to continue – if not accelerate – going forward. Operating expenses were higher than expected, but sensible given that the company is still developing markets, gaining share and launching new products in new markets.

In essence, we "buy into" the strategy of "striking while the iron is hot" as opposed to "starving the business" in favor of modest earnings or lower net losses. We have seen the former strategy work before in small-cap med-tech – including Spectranetics, which decided to develop the PAD market and strive for share gain in this market, successfully we might add – over the past half decade, during which time the stock has more than quintupled from its lows in 2003.

SenoRx is unique in that it is the only independent company that possesses next-generation devices that address the entire continuum of care in breast cancer: diagnosis/biopsy, marking, excision and treatment solutions. We view the minimally invasive biopsy and breast brachytherapy opportunities as particularly attractive as long-term growth markets in the medical device arena.

Minimally invasive biopsy and breast brachytherapy opportunities are particularly attractive to us. We estimate the percutaneous vacuum-assisted biopsy market at $195.3 million in 2007, with growth of about 15% per annum. We project growth in the number of ultrasound-guided vacuum-assisted biopsies could approximate 17.4% (2005-2009) and note that this could be conservative as a result of the aforementioned drivers for ultrasound usage in general. SenoRx's EnCor vacuum-assisted biopsy system is state-of-the art, and we expect sales gains for this system to exceed market growth handily over our forecast period. The breast brachytherapy market is nascent at only $44.3 million estimated for 2007 but expected to grow robustly over a five year period. Contura, the company's multi-lumen radiation balloon for breast brachytherapy, is in the initial stages of its full commercial launch and we expect a steep revenue ramp beginning in 2008.

Classic "triple-play" med-tech growth story. SenoRx has driven impressive revenue growth and product innovation since its inception in 1998. We think the best days are ahead of the company owing to what we identify as a classic "triple-play" small-cap company growth formula, namely: 1) differentiated technology addressing attractive segments of a growth market (in this case the breast device market), 2) strong R&D culture that has produced a strong new product pipeline, and 3) ramping direct sales force.

Contura could be a major catalyst for SenoRx, as well as the localized radiation therapy market as a whole in coming years. We believe SenoRx's device surpasses the capabilities of and addresses a larger patient population than other localized brachytherapy devices. It is the only multi-lumen balloon therapy on the market (more precise targeting and possibly higher reimbursement) and its "on-board" vacuum and proprietary balloon material add to its efficacy and differentiation, in our view.

Strong product pipeline. The fruits of the company's strong R&D culture seem poised to bear additional fruit in the coming months and years. In addition to Contura, the company plans several additional sizes and iterations during 2008, with the European launch of SenoSonix also expected soon. Also, we expect SenoRx to introduce two innovative breast excision devices (Single Step and Shape Select) in 2009. We think the Single Step – which has already received FDA 510k clearance – could fulfill an unmet need for surgeons, as well as potentially acting as an adjunct driver of Contura sales, as it creates a "smooth" lesion cavity for enhanced placement of these balloon catheters. The Shape Select, also FDA-cleared, is designed for use in reconstructive breast procedures. We also look forward to the introduction of a cordless model in the EnCor family, which we think will be popular with physicians and OR staffs. Lastly, we expect the company to continue expanding its market-leading marker portfolio over the next two years.

Valuation

The broad small-cap med-tech comp group (composed of over 60 companies with market caps under $1.5 billion) currently trades at a mean EV/ sales multiple of 5.1x (excluding high and low outliers) relative to C2007E revenue. SenoRx' 2007 revenue grew to $35 million, representing an increase of 37% versus 2006 levels and we project it to grow to $49.5M in 2008 representing a 41.4% Y/Y increase. While this revenue growth is strong and could justify an in-line or even premium multiple relative to the comp group, we choose to apply a 22% discount to the group average (reflecting conservatism perhaps) to derive a target EV/Sales multiple of 4.0x, which we apply to our $49.5M 2008 sales estimate to derive our price target of $12.25/share 12 months hence.

Figure 1: Matrix of discount rates and implied share price target

		Discount to Comp Group		
		17%	22%	27%
Target EV/Sales multiple for SENO common		4.2x	4.0x	3.7x
Implied Price Target on SENO common		$12.94	$12.25	$11.55
Financial Metrics Used in Analysis				
Broad small-cap medical device EV/Sales multiple (C2007E)	5.1x			
SENO 2008E Sales ($ mil)	$49.5			
Cash ($ mil)	$28			
Debt ($ mil)	$2			
Diluted shares outstanding (mil)	18			

Source: Canaccord Adams.

Investment risks

Financial and distribution strength of VAB biopsy competitors, uncertainty over which technology will "win" in breast brachytherapy, increased use of MRI and ultrasound, reimbursement and potential for pricing erosion.

Figure 2: Quarterly income statement

INCOME STATEMENT
Fiscal Year End - Dec
($mil - except per share data)

	CY 2004	CY 2005	CY 2006	2007 Mar	2007 Jun	2007 Sep	2007 Dec	CY 2007	2008E MarE	2008E JunE	2008E SepE	2008E DecE	CY 2008E	CY 2009E
Total revenue	$ 13.8	$ 19.3	$ 25.5	$ 7.7	$ 8.1	$ 8.9	$ 10.3	$ 35.0	$ 10.7	$ 11.7	$ 12.5	$ 14.6	$ 49.5	$ 67.2
Cost of goods sold	6.4	10.1	13.5	3.5	3.5	3.6	4.5	15.1	4.4	4.6	4.7	5.2	18.9	22.8
Gross profit	7.3	9.1	12.0	4.2	4.6	5.4	5.8	19.9	6.3	7.1	7.8	9.4	30.6	44.4
R&D (including options exp)	4.8	4.9	5.3	1.5	1.6	1.6	1.7	6.4	1.7	1.8	1.9	1.9	7.2	8.1
Selling & marketing (incl. option	7.5	10.1	15.0	4.3	4.4	4.4	5.9	19.0	6.0	6.1	6.1	6.6	24.8	27.7
G&A (incl. options)	1.7	2.1	2.0	0.8	1.1	1.2	1.1	4.2	1.1	1.1	1.2	1.3	4.6	5.4
Operating income/(Loss)	**(6.7)**	**(8.0)**	**(10.4)**	**(2.4)**	**(2.6)**	**(1.8)**	**(2.9)**	**(9.6)**	**(2.5)**	**(1.9)**	**(1.3)**	**(0.4)**	**(6.1)**	**3.2**
Other, net	0.0	0.1	0.1	0.8	0.3		-	1.1	-	-	-	-	-	-
Net interest income/(expense)	(0.2)	(0.7)	(1.0)	(0.5)	0.1	0.1	0.2	(0.1)	0.3	0.3	0.2	0.3	1.0	1.0
Pretax income	**(6.8)**	**(8.6)**	**(11.3)**	**(2.1)**	**(2.1)**	**(1.7)**	**(2.7)**	**(8.7)**	**(2.2)**	**(1.6)**	**(1.1)**	**(0.2)**	**(5.1)**	**4.2**
Tax expense	0.1	0.0	-	-	-	-	-	-	-	-	-	-	-	-
Tax Rate	n/a	n/a	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Net income/(loss) - Pro forma	**(6.9)**	**(8.6)**	**(11.3)**	**(2.1)**	**(2.1)**	**(1.7)**	**(2.7)**	**(8.7)**	**(2.2)**	**(1.6)**	**(1.1)**	**(0.2)**	**(5.1)**	**4.2**
Extraordinary charges (net of tax)			(4.1)				(1.3)	(1.3)						
Net income/(loss) - GAAP	(6.9)	(8.6)	(15.4)	(2.1)	(2.1)	(1.7)	(4.0)	(9.9)	(2.2)	(1.6)	(1.1)	(0.2)	(5.1)	4.2
Shares outstanding	17.8	17.8	17.8	10.7	13.9	17.1	17.2	14.7	17.6	17.8	17.9	18.1	17.8	18.2
EPS - Pro forma	**$ (0.39)**	**$ (0.48)**	**$ (0.63)**	**$ (0.20)**	**$ (0.15)**	**$ (0.10)**	**$ (0.16)**	**$ (0.59)**	**$ (0.12)**	**$ (0.09)**	**$ (0.06)**	**$ (0.01)**	**$ (0.28)**	**$ 0.23**
EPS - GAAP	$ -	$ -	$ 6.51	$ (0.20)	$ (0.15)	$ (0.10)	$ (0.23)	$ (0.68)	$ (0.12)	$ (0.09)	$ (0.06)	$ (0.01)	$ (0.28)	$ 0.23
Margin Analysis														
Gross Margin	53.3%	47.5%	47.1%	54.1%	57.0%	60.1%	56.0%	56.8%	58.9%	60.5%	62.5%	64.4%	61.8%	66.0%
Operating Margin	-48.5%	-41.6%	-40.8%	-31.0%	-31.4%	-20.1%	-28.3%	-27.5%	-23.0%	-15.9%	-10.7%	-2.9%	-12.3%	4.8%
Pretax Margin	-49.6%	-44.7%	-44.1%	-27.4%	-26.3%	-19.0%	-26.5%	-24.7%	-20.4%	-13.7%	-8.8%	-1.1%	-10.2%	6.3%
Net Margin	-50.1%	-44.8%	-44.1%	-27.4%	-26.3%	-19.0%	-26.5%	-24.7%	-20.4%	-13.7%	-8.8%	-1.1%	-10.2%	6.3%
R & D - % Revenue	34.8%	25.5%	20.9%	19.1%	20.3%	17.7%	16.1%	18.1%	15.9%	15.5%	14.8%	12.8%	14.6%	12.0%
Selling & Marketing - % Revenue	54.6%	52.7%	59.0%	55.8%	54.6%	48.9%	57.6%	54.3%	56.0%	51.6%	49.0%	45.5%	50.1%	41.2%
G & A - % Revenue	12.4%	11.0%	8.0%	10.2%	13.6%	13.5%	10.6%	11.9%	10.0%	9.4%	9.4%	9.0%	9.4%	8.0%
Growth (Y/Y)														
Revenue	n/a	40.0%	32.5%	32.0%	28.4%	45.0%	43.1%	37.4%	39.0%	44.5%	40.7%	41.3%	41.4%	35.8%
COGS	n/a	57.5%	33.6%	14.6%	14.3%	7.7%	11.7%	12.0%	24.3%	32.8%	32.1%	14.1%	25.0%	20.7%
Gross Income	n/a	24.7%	31.2%	51.5%	41.5%	88.1%	83.9%	65.9%	51.4%	53.3%	46.3%	62.7%	53.8%	45.0%
Operating Income	n/a	20.2%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Net Income	n/a	125.2%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
EPS	n/a	125.2%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

Source: Company reports and Canaccord Adams estimates

Figure 3: Revenues by segment

REVENUE MODEL

	CY 2004	CY 2005	CY 2006	2007 Mar	2007 Jun	2007 Sep	2007 Dec	CY 2007	2008E MarE	2008E JunE	2008E SepE	2008E DecE	CY 2008E	CY 2009E
Unit Model														
Disposables														
EnCor Biopsy	4,693	24,183	44,829	14,446	16,628	16,378	19,180	66,632	20,369	23,445	22,913	26,823	93,551	121,420
SenoCor Biopsy	3,333	3,333	3,823	997	1,095	995	1,212	4,300	1,132	1,243	1,129	1,376	4,880	5,466
Units - Total Biopsy	8,026	27,516	48,652	15,443	17,723	17,372	20,393	70,932	21,501	24,689	24,042	28,200	98,431	126,886
Captive Markers	19,546	26,817	39,575	13,650	14,363	16,490	19,106	63,609	19,383	20,036	22,674	24,838	86,931	112,275
Non-Captive Markers	119,718	119,718	124,300	32,652	31,200	30,792	32,640	127,285	33,632	32,136	31,716	33,619	131,103	133,856
Units - Total Markers	139,265	146,535	163,875	46,302	45,563	47,282	51,746	190,893	53,015	52,172	54,390	58,457	218,034	246,131
Single Step	-	-	-	-	-	-	-	-	-	-	250	250	500	3,250
Shape Select	-	-	-	-	-	-	-	-	-	-	250	300	550	3,150
Anchor Guide	1,128	1,343	775	200	140	200	200	740	-	-	-	-	-	-
Contura radiation balloon therapy	-	-	-	-	10	71	195	276	341	456	661	935	2,392	5,375
GED	-	-	-	-	-	-	-	-	-	-	-	-	-	500
Gamma Detection	72	56	82	21	11	20	24	75	27	27	28	29	111	130
								-					-	-
Capital Equipment														
EnCor Biopsy Equipment Sold	89	89	60	24	30	40	50	144	39	39	38	38	154	135
EnCor Biopsy Equipment PSA	30	30	89	19	16	10	30	75	16	16	16	20	68	82
Units - EnCor Biopsy Equipment Total	119	119	149	43	46	50	80	219	55	55	54	58	222	217
Units - SenoCor Biopsy Equipment	7	7	3	1	1	1	1	4	1	1	1	1	4	4
Average Selling Prices														
EnCor Biopsy	$ 240	$ 230	$ 230	$ 230	$ 230	$ 230	$ 230	$ 230	$ 230	$ 230	$ 230	$ 230	$ 230	$ 230
SenoCor Biopsy	$ 180	$ 180	$ 180	$ 180	$ 180	$ 180	$ 180	$ 180	$ 180	$ 180	$ 180	$ 180	$ 180	$ 180
Captive Markers	$ 71	$ 71	$ 71	$ 71	$ 71	$ 71	$ 71	$ 71	$ 71	$ 71	$ 71	$ 71	$ 71	$ 71
Non-captive Markers	$ 71	$ 71	$ 71	$ 71	$ 71	$ 71	$ 71	$ 71	$ 71	$ 71	$ 71	$ 71	$ 71	$ 71
EnCor Biopsy Equipment Sold	$ 20,500	$ 20,500	$ 19,281	$ 20,000	$ 20,097	$ 25,289	$ 23,550	$ 22,234	$ 22,000	$ 22,000	$ 22,000	$ 22,000	$ 22,000	$ 21,000
SenoCor Biopsy Equipment	$ 17,500	$ 17,500	$ 17,500	$ 17,500	$ 17,500	$ 17,500	$ 17,500	$ 17,500	$ 17,500	$ 17,500	$ 17,500	$ 17,500	$ 17,500	$ 17,500
Single Step	$ 300	$ 300	$ 300	$ 300	$ 300	$ 300	$ 300	$ 300	$ 300	$ 300	$ 300	$ 300	$ 300	$ 300
Shape Select	$ 100	$ 100	$ 100	$ 100	$ 100	$ 100	$ 100	$ 100	$ 100	$ 100	$ 100	$ 100	$ 100	$ 100
Anchor Guide	$ 175	$ 175	$ 175	$ 175	$ 175	$ 175	$ 175	$ 175	$ 175	$ 175	$ 175	$ 175	$ 175	$ 175
Contura radiation balloon therapy	$ 2,700	$ 2,700	$ 2,700	$ 2,633	$ 2,500	$ 2,634	$ 1,750	$ 2,379	$ 2,013	$ 2,314	$ 2,627	$ 2,692	$ 2,412	$ 2,616
GED	-	-	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 500
Gamma Detection	$ 18,875	$ 18,875	$ 18,494	$ 18,000	$ 18,000	$ 18,000	$ 18,000	$ 18,000	$ 18,000	$ 18,000	$ 18,000	$ 18,000	$ 18,000	$ 18,000
Revenue ($ in millions)														
Encor Biopsy Equipment			$ 1.2	$ 0.5	$ 0.6	$ 1.0	$ 1.2	$ 3.3	$ 0.9	$ 0.9	$ 0.8	$ 0.8	$ 3.4	$ 2.8
Senocor Biopsy Equipment			$ 0.1	$ 0.0	$ 0.0	$ 0.0	$ 0.0	$ 0.1	$ 0.0	$ 0.0	$ 0.0	$ 0.0	$ 0.1	$ 0.1
Encor Biopsy	$ 1.1	$ 5.6	$ 10.3	$ 3.3	$ 3.8	$ 3.8	$ 4.4	$ 15.3	$ 4.7	$ 5.4	$ 5.3	$ 6.2	$ 21.5	$ 27.9
Senocor Biopsy	$ 0.6	$ 0.6	$ 0.7	$ 0.2	$ 0.2	$ 0.2	$ 0.2	$ 0.8	$ 0.2	$ 0.2	$ 0.2	$ 0.2	$ 0.9	$ 1.0
Biopsy Products	**$ 1.7**	**$ 6.2**	**$ 11.0**	**$ 3.5**	**$ 4.0**	**$ 3.9**	**$ 4.6**	**$ 16.1**	**$ 4.9**	**$ 5.6**	**$ 5.5**	**$ 6.4**	**$ 22.4**	**$ 28.9**
Captive Markers	$ 1.4	$ 1.9	$ 2.8	$ 1.0	$ 1.0	$ 1.2	$ 1.4	$ 4.5	$ 1.4	$ 1.4	$ 1.6	$ 1.8	$ 6.2	$ 8.0
Non-captive Markers	$ 8.5	$ 8.5	$ 8.8	$ 2.3	$ 2.2	$ 2.2	$ 2.3	$ 9.0	$ 2.4	$ 2.3	$ 2.3	$ 2.4	$ 9.3	$ 9.5
Marker Products	**$ 9.9**	**$ 10.4**	**$ 11.6**	**$ 3.3**	**$ 3.2**	**$ 3.4**	**$ 3.7**	**$ 13.6**	**$ 3.8**	**$ 3.7**	**$ 3.9**	**$ 4.2**	**$ 15.5**	**$ 17.5**
Biopsy Equipment	$ 0.6	$ 1.4	$ 1.2	$ 0.5	$ 0.6	$ 1.0	$ 1.2	$ 3.3	$ 0.9	$ 0.9	$ 0.9	$ 0.9	$ 3.5	$ 2.9
Single Step	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 0.1	$ 0.1	$ 0.2	$ 1.0
Shape Select	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 0.0	$ 0.0	$ 0.1	$ 0.3
Anchor Guide	$ 0.2	$ 0.2	$ 0.1	$ 0.0	$ 0.0	$ 0.0	$ 0.0	$ 0.1	$ -	$ -	$ -	$ -	$ -	$ -
Excision/Therapy	**$ 0.2**	**$ 0.2**	**$ 0.1**	**$ 0.0**	**$ 0.0**	**$ 0.0**	**$ 0.0**	**$ 0.1**	**$ -**	**$ -**	**$ 0.1**	**$ 0.1**	**$ 0.2**	**$ 1.3**
Contura radiation balloon therapy	**$ -**	**$ -**	**$ -**	**$ -**	**$ 0.0**	**$ 0.2**	**$ 0.3**	**$ 0.6**	**$ 0.7**	**$ 1.1**	**$ 1.7**	**$ 2.5**	**$ 6.0**	**$ 14.0**
GED	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ 0.3**
Gamma Detection	**$ 1.4**	**$ 1.1**	**$ 1.6**	**$ 0.4**	**$ 0.2**	**$ 0.4**	**$ 0.4**	**$ 1.4**	**$ 0.5**	**$ 0.5**	**$ 0.5**	**$ 0.5**	**$ 2.0**	**$ 2.3**
Total Revenue	**$ 13.8**	**$ 19.3**	**$ 25.5**	**$ 7.7**	**$ 8.1**	**$ 8.9**	**$ 10.3**	**$ 35.0**	**$ 10.7**	**$ 11.7**	**$ 12.5**	**$ 14.6**	**$ 49.5**	**$ 67.2**
REVENUE ANALYSIS - (% of Total Revenue)														
Biopsy Products	12.6%	32.0%	43.1%	45.5%	49.5%	44.3%	44.9%	46.0%	45.7%	47.9%	43.7%	44.1%	45.2%	43.0%
Marker Products	71.9%	54.0%	45.5%	42.7%	39.8%	37.7%	35.6%	38.7%	35.2%	31.6%	30.8%	28.5%	31.3%	26.0%
Biopsy Equipment	4.2%	7.2%	4.8%	6.5%	7.6%	11.6%	11.6%	9.5%	8.2%	7.5%	6.8%	5.9%	7.0%	4.3%
Excision/Therapy	1.4%	1.2%	0.5%	0.5%	0.3%	0.4%	0.3%	0.4%	0.0%	0.0%	0.8%	0.7%	0.4%	1.9%
Contura radiation balloon therapy	0.0%	0.0%	0.0%	0.0%	0.3%	2.1%	3.3%	1.6%	6.4%	9.0%	13.9%	17.3%	12.1%	20.9%
Gamma Detection	9.9%	5.5%	6.1%	4.9%	2.4%	4.0%	4.2%	3.9%	4.5%	4.1%	4.0%	3.6%	4.0%	3.5%
	100.0%	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**99.6%**
REVENUE Growth - (Year-over-Year)														
Biopsy Products	n/a	257.1%	78.4%	52.3%	52.3%	39.8%	43.1%	46.4%	39.6%	39.7%	38.7%	38.6%	39.1%	29.1%
Marker Products	n/a	5.2%	11.8%	19.3%	11.7%	18.8%	16.3%	16.5%	14.5%	14.5%	15.0%	13.0%	14.2%	12.9%
Biopsy Equipment	n/a	139.6%	-12.1%	61.8%	55.9%	241.9%	461.4%	174.1%	76.0%	41.1%	-17.1%	-28.6%	3.5%	-16.0%
Excision/Therapy	n/a	19.0%	-42.3%	0.0%	-20.0%	33.3%	-20.0%	-4.5%	-100.0%	-100.0%	185.7%	200.0%	58.3%	529.3%
Contura radiation balloon therapy	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	827.7%	637.5%	983.2%	134.0%
Gamma Detection	n/a	-22.0%	46.6%	-13.1%	-44.6%	-8.9%	13.0%	-12.7%	28.6%	149.4%	43.2%	20.8%	47.3%	17.0%
Total Revenue	**n/a**	**40.0%**	**32.7%**	**32.0%**	**28.6%**	**40.0%**	**46.5%**	**37.2%**	**39.0%**	**44.5%**	**40.7%**	**41.3%**	**41.4%**	**35.8%**

Source: Company reports and Canaccord Adams estimates

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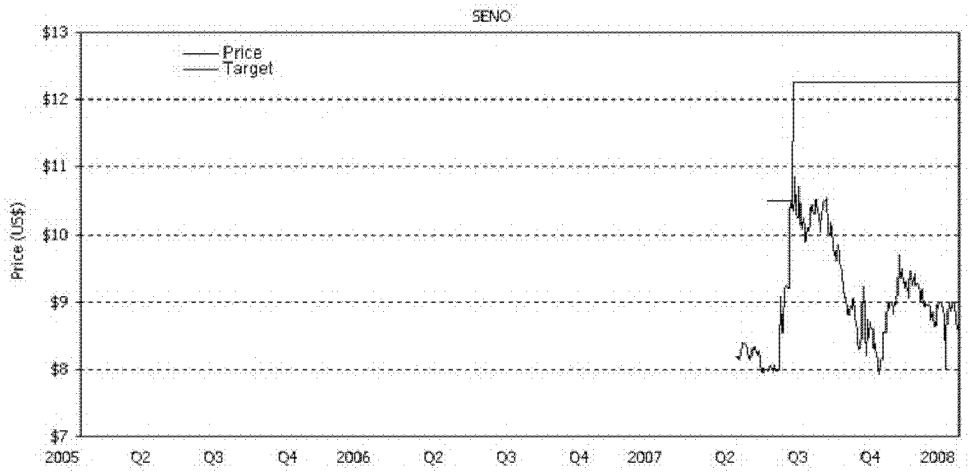
Analyst Certification: Each authoring analyst of Canaccord Adams whose name appears on the front page of this investment research hereby certifies that (i) the recommendations and opinions expressed in this investment research accurately reflect the authoring analyst's personal, independent and objective views about any and all of the designated investments or relevant issuers discussed herein that are within such authoring analyst's coverage universe and (ii) no part of the authoring analyst's compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed by the authoring analyst in the investment research.

Site Visit: An analyst has visited the issuer's material operations in Aliso Viejo, California. No payment or reimbursement was received from the issuer for the related travel costs.

Price Chart:*



	Date	Analyst	Rating	Target Price
1)	05/08/07	JM	Buy	10.50
2)	06/07/07	JM	Buy	12.25

* Price charts assume event 1 indicates initiation of coverage or the beginning of the measurement period.

Distribution of Ratings:
Global Stock Ratings
(as of 1 February 2008)

	Coverage Universe		IB Clients
Rating	#	%	%
Buy	313	60.3%	43.1%
Speculative Buy	62	11.9%	71.0%
Hold	128	24.7%	24.2%
Sell	16	3.1%	6.3%
	519	100.0%	

Canaccord Ratings System:

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Company	Disclosure
SenoRx	1A, 2, 3, 5, 7

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